

DRUG LAW DEFINITIONS - AMENDMENTS

2010 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Trisha S. Beck

Senate Sponsor: Peter C. Knudson

LONG TITLE

General Description:

This bill modifies health care chapters in Title 58, Occupations and Professions, to provide consistency in specified definitions used in these chapters.

Highlighted Provisions:

This bill:

- amends the Utah Controlled Substances Act, the Utah Medical Practice Act, the Pharmacy Practice Act, the Utah Osteopathic Medical Practice Act, and the Naturopathic Physician Practice Act to provide consistency in the use of definitions, including those for "prescribe," "prescription device," and "drug."

Monies Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-102, as last amended by Laws of Utah 2005, Chapter 160

58-17b-606, as last amended by Laws of Utah 2006, Chapter 90

58-17b-612, as last amended by Laws of Utah 2007, Chapter 279

58-37-2, as last amended by Laws of Utah 2009, Chapter 42

58-67-102, as last amended by Laws of Utah 2008, Chapter 382

58-68-102, as last amended by Laws of Utah 2008, Chapter 382

58-71-102, as last amended by Laws of Utah 2009, Chapter 42

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

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

58-17b-102. Definitions.

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

(1) "Administering" means:

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

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

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

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

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

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

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

58 all transaction information.

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

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

66 (8) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created
67 in Section 58-17b-201.

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

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

75 (11) "Class B pharmacy":

76 (a) means a pharmacy located in Utah:

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

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

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

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

83 (12) "Class C pharmacy" means a pharmacy located in Utah that is authorized to
84 engage in the manufacture, production, wholesale, or distribution of drugs or devices.

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

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

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

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

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

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

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

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

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

109 (b) "Compounding" does not include:

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

112 (ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a
113 dosage form which is regularly and commonly available from a manufacturer in quantities and

114 strengths prescribed by a practitioner; or

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

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

120 (20) "Controlled substance" has the same definition as in Section 58-37-2.

121 ~~[(21) "Device" means an instrument, apparatus, implement, machine, contrivance,
122 implant, in vitro reagent, or other similar or related article, including any component part or
123 accessory, which is required under federal or state law to be prescribed by a practitioner and
124 dispensed by a pharmacist or pharmacy intern.]~~

125 ~~[(22)]~~ (21) "Dietary supplement" has the same meaning as Public Law Title 103,
126 Chapter 417, Sec. 3a(ff) which is incorporated by reference.

127 ~~[(23)]~~ (22) "Dispense" means the interpretation, evaluation, and implementation of a
128 prescription drug order or device or nonprescription drug or device under a lawful order of a
129 practitioner in a suitable container appropriately labeled for subsequent administration to or use
130 by a patient, research subject, or an animal.

131 ~~[(24)]~~ (23) "Distribute" means to deliver a drug or device other than by administering
132 or dispensing.

133 ~~[(25)]~~ (24) (a) "Drug" means:

134 ~~[(a) a substance recognized as a drug in any official compendium, or supplement
135 thereto, designated from time to time by the division in collaboration with the board for use in
136 the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals,
137 excluding nonprescription drugs or dietary supplements;]~~

138 ~~[(b) a drug or device that is required by any applicable federal or state law or rule to be
139 dispensed on prescription only or is restricted to use by practitioners only;]~~

140 ~~[(c) substances other than food intended to affect the structure or any function of the
141 body of humans or other animals, excluding nonprescription dietary supplements; and]~~

142 ~~[(d) substances intended for use as a component of any substance specified in~~
143 ~~Subsection (25)(a), (b), or (c).]~~

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

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

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

152 (iv) substances intended for use as a component of any substance specified in
153 Subsections (24)(a)(i), (ii), (iii), and (iv).

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

155 ~~[(26)]~~ (25) "Drug product equivalent" means a drug product that is designated as the
156 therapeutic equivalent of another drug product in the Approved Drug Products with
157 Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research
158 of the Federal Food and Drug Administration.

159 ~~[(27)]~~ (26) "Drug regimen review" includes the following activities:

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

161 (i) known allergies;

162 (ii) rational therapy-contraindications;

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

164 (iv) reasonable directions for use;

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

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

169 (i) drug-drug;

- 170 (ii) drug-food;
- 171 (iii) drug-disease; and
- 172 (iv) adverse drug reactions; and
- 173 (d) evaluation of the prescription drug order and patient record for proper utilization,
- 174 including over- or under-utilization, and optimum therapeutic outcomes.

175 [~~(28)~~] (27) "Drug sample" means a prescription drug packaged in small quantities
176 consistent with limited dosage therapy of the particular drug, which is marked "sample", is not
177 intended to be sold, and is intended to be provided to practitioners for the immediate needs of
178 patients for trial purposes or to provide the drug to the patient until a prescription can be filled
179 by the patient.

180 [~~(29)~~] (28) "Electronic signature" means a trusted, verifiable, and secure electronic
181 sound, symbol, or process attached to or logically associated with a record and executed or
182 adopted by a person with the intent to sign the record.

183 [~~(30)~~] (29) "Electronic transmission" means transmission of information in electronic
184 form or the transmission of the exact visual image of a document by way of electronic
185 equipment.

186 [~~(31)~~] (30) "Extern" means a college of pharmacy student enrolled in a college
187 coordinated practical experience program in a health care setting under the supervision of a
188 preceptor, as defined in this act, and approved by a college of pharmacy.

189 [~~(32)~~] (31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to
190 inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
191 under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

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

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

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

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

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

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

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

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

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

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

216 (38) "Misbranded drug or device" means a drug or device considered misbranded under
217 21 U.S.C.S. Sec. 352 (2003).

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

219 (i) may be sold without a prescription; and [~~which~~]

220 (ii) is labeled for use by the consumer in accordance with federal law [~~and~~].

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

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

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

225 (42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located

226 outside the state that is licensed and in good standing in another state, that:

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

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

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

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

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

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

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

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

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

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

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

253 (iii) arresting or slowing a disease process.

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

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

259 (47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility
260 engaged in the business of wholesale vending or selling of any prescription drug or device to
261 other than the consumer or user of the prescription drug or device, which the pharmaceutical
262 facility has not produced, manufactured, compounded, or dispensed.

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

265 (i) intracompany sales;

266 (ii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,
267 purchase or trade a prescription drug or device between hospitals or other health care facilities
268 that are under common ownership or control of the management and operation of the facilities;

269 (iii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,
270 purchase, or trade a prescription drug or device for emergency medical reasons, or to supply
271 another pharmaceutical facility to alleviate a temporary shortage; or

272 (iv) the distribution of a prescription drug or device as a sample by representatives of a
273 manufacturer.

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

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

280 (50) "Pharmacist preceptor" means a licensed pharmacist in good standing with two or
281 more years of licensed experience. The preceptor serves as a teacher, example of professional

282 conduct, and supervisor of interns in the professional practice of pharmacy.

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

284 (a) drugs are dispensed;

285 (b) pharmaceutical care is provided;

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

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

288 (52) "Pharmacy benefits manager or coordinator" means a person or entity that
289 administers the prescription drug or device portion of a health insurance plan on behalf of a
290 self-insured employer, insurance company, health maintenance organization, or other plan
291 sponsor, as defined by rule.

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

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

296 (55) (a) "Practice as a licensed pharmacy technician" means engaging in practice as a
297 pharmacy technician under the general supervision of a licensed pharmacist and in accordance
298 with a scope of practice defined by division rule made in collaboration with the board.

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

300 (i) performing a drug utilization review, prescription drug order clarification from a
301 prescriber, final review of the prescription and prescribed drug prepared for dispensing,
302 dispensing of the drug, or counseling a patient with respect to a prescription drug;

303 (ii) counseling regarding nonprescription drugs and dietary supplements unless
304 delegated by the supervising pharmacist; or

305 (iii) receiving new prescription drug orders when communicating telephonically or
306 electronically unless the original information is recorded so the pharmacist may review the
307 prescription drug order as transmitted.

308 (56) "Practice of pharmacy" includes the following:

309 (a) providing pharmaceutical care;

- 310 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy
311 practice agreement;
- 312 (c) compounding, packaging, labeling, dispensing, administering, and the coincident
313 distribution of prescription drugs or devices, provided that the administration of a prescription
314 drug or device is:
- 315 (i) pursuant to a lawful order of a practitioner when one is required by law; and
316 (ii) in accordance with written guidelines or protocols:
- 317 (A) established by the licensed facility in which the prescription drug or device is to be
318 administered on an inpatient basis; or
- 319 (B) approved by the division, in collaboration with the board and the Physicians
320 Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be
321 administered on an outpatient basis solely by a licensed pharmacist;
- 322 (d) participating in drug utilization review;
- 323 (e) ensuring proper and safe storage of drugs and devices;
- 324 (f) maintaining records of drugs and devices in accordance with state and federal law
325 and the standards and ethics of the profession;
- 326 (g) providing information on drugs or devices, which may include advice relating to
327 therapeutic values, potential hazards, and uses;
- 328 (h) providing drug product equivalents;
- 329 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
330 technicians;
- 331 (j) providing patient counseling, including adverse and therapeutic effects of drugs;
- 332 (k) providing emergency refills as defined by rule;
- 333 (l) telepharmacy; and
- 334 (m) formulary management intervention.
- 335 (57) "Practice of telepharmacy" means the practice of pharmacy through the use of
336 telecommunications and information technologies.
- 337 (58) "Practice of telepharmacy across state lines" means the practice of pharmacy

338 through the use of telecommunications and information technologies that occurs when the
339 patient is physically located within one jurisdiction and the pharmacist is located in another
340 jurisdiction.

341 (59) "Practitioner" means an individual currently licensed, registered, or otherwise
342 authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of
343 professional practice.

344 (60) "Prescribe" means to issue a prescription:

345 (a) orally or in writing; or

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

348 [~~(60)~~ (61) "Prescription" means an issued:

349 [~~(a)~~ issued by a licensed practitioner;]

350 [~~(i)~~ orally, in writing, by telephone, facsimile transmission, computer, or other
351 electronic means of communication as defined by division rule;]

352 [~~(ii)~~ in the course of the practitioner's professional practice; or]

353 [~~(iii)~~ by collaborative pharmacy practice agreement; and]

354 [~~(b)~~ for a controlled substance, other prescription drug, or device with the intent that
355 the controlled substance, prescription drug, or device will be used by a patient or an animal.]

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

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

360 [~~(61)~~ "Prescription drug or device" means:]

361 [~~(a)~~ a legend drug or device; or]

362 [~~(b)~~ a drug or device that is required by an applicable federal or state law or rule to be
363 dispensed on prescription only or is restricted to use by practitioners only.]

364 (62) "Prescription device" means an instrument, apparatus, implement, machine,
365 contrivance, implant, in vitro reagent, or other similar or related article, and any component

366 part or accessory, which is required under federal or state law to be prescribed by a practitioner
367 and dispensed by or through a person or entity licensed under this chapter or exempt from
368 licensure under this chapter.

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

371 [~~(62)~~] (64) "Retail pharmacy" means a pharmaceutical facility dispensing prescription
372 drugs and devices to the general public.

373 [~~(63)~~] (65) "Self-audit" means an internal evaluation of a pharmacy to determine
374 compliance with this chapter.

375 [~~(64)~~] (66) "Supervising pharmacist" means a pharmacist who is overseeing the
376 operation of the pharmacy during a given day or shift.

377 [~~(65)~~] (67) "Supportive personnel" means unlicensed individuals who:

378 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
379 pharmacy technician in nonjudgmental duties not included in the definition of the practice of
380 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
381 those duties may be further defined by division rule adopted in collaboration with the board;
382 and

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

385 [~~(66)~~] (68) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

386 [~~(67)~~] (69) "Unprofessional conduct" is as defined in Sections 58-1-501 and
387 58-17b-502 and may be further defined by rule.

388 [~~(68)~~] (70) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
389 dispenses drugs intended for use by animals or for sale to veterinarians for the administration
390 for animals.

391 Section 2. Section **58-17b-606** is amended to read:

392 **58-17b-606. Restrictive drug formulary prohibited.**

393 (1) As used in this section:

394 (a) "Generic form" means a prescription drug that is available in generic form and has
395 an A rating in the United States Pharmacopeia and Drug Index.

396 (b) "Legend drug" [~~means any drug that requires a prescription under state or federal~~
397 ~~law~~] has the same meaning as prescription drug.

398 [(~~e~~)] (b) "Restrictive drug formulary" means a list of legend drugs, other than drugs for
399 cosmetic purposes, that are prohibited by the Department of Health from dispensation, but are
400 approved by the Federal Food and Drug Administration.

401 (2) A practitioner may prescribe legend drugs in accordance with this chapter that, in
402 his professional judgment and within the lawful scope of his practice, he considers appropriate
403 for the diagnosis and treatment of his patient.

404 (3) Except as provided in Subsection (4), the Department of Health may not maintain a
405 restrictive drug formulary that restricts a physician's ability to treat a patient with a legend drug
406 that has been approved and designated as safe and effective by the Federal Food and Drug
407 Administration, except for drugs for cosmetic purposes.

408 (4) When a multisource legend drug is available in the generic form, the Department of
409 Health may only reimburse for the generic form of the drug unless the treating physician
410 demonstrates to the Department of Health a medical necessity for dispensing the nongeneric,
411 brand-name legend drug.

412 (5) The Department of Health pharmacists may override the generic mandate
413 provisions of Subsection (4) if a financial benefit will accrue to the state.

414 (6) This section does not affect the state's ability to exercise the exclusion options
415 available under the Federal Omnibus Budget Reconciliation Act of 1990.

416 Section 3. Section **58-17b-612** is amended to read:

417 **58-17b-612. Supervision -- Pharmacist-in-charge.**

418 (1) (a) Any pharmacy, except a wholesaler, distributor, out-of-state mail service
419 pharmacy, or class E pharmacy, shall be under the general supervision of at least one
420 pharmacist licensed to practice in Utah. One pharmacist licensed in Utah shall be designated
421 as the pharmacist-in-charge, whose responsibility it is to oversee the operation of the pharmacy.

422 (b) Notwithstanding Subsection 58-17b-102[(64)](66), a supervising pharmacist does
423 not have to be in the pharmacy or care facility but shall be available via a telepharmacy system
424 for immediate contact with the supervised pharmacy technician or pharmacy intern if:

- 425 (i) the pharmacy is located in:
 - 426 (A) a remote rural hospital, as defined in Section 26-21-13.6; or
 - 427 (B) a clinic located in a remote rural county with less than 20 people per square mile;
- 428 (ii) the supervising pharmacist described in Subsection (1)(a) is not available; and
- 429 (iii) the telepharmacy system maintains records and files quarterly reports as required
430 by division rule to assure that patient safety is not compromised.

431 (2) Each out-of-state mail service pharmacy shall designate and identify to the division
432 a pharmacist holding a current license in good standing issued by the state in which the
433 pharmacy is located and who serves as the pharmacist-in-charge for all purposes under this
434 chapter.

435 Section 4. Section **58-37-2** is amended to read:

436 **58-37-2. Definitions.**

437 (1) As used in this chapter:

438 (a) "Administer" means the direct application of a controlled substance, whether by
439 injection, inhalation, ingestion, or any other means, to the body of a patient or research subject
440 by:

- 441 (i) a practitioner or, in the practitioner's presence, by the practitioner's authorized agent;
- 442 or
- 443 (ii) the patient or research subject at the direction and in the presence of the
444 practitioner.

445 (b) "Agent" means an authorized person who acts on behalf of or at the direction of a
446 manufacturer, distributor, or practitioner but does not include a motor carrier, public
447 warehouseman, or employee of any of them.

448 (c) "Consumption" means ingesting or having any measurable amount of a controlled
449 substance in a person's body, but this Subsection (1)(c) does not include the metabolite of a

450 controlled substance.

451 (d) "Continuing criminal enterprise" means any individual, sole proprietorship,
452 partnership, corporation, business trust, association, or other legal entity, and any union or
453 groups of individuals associated in fact although not a legal entity, and includes illicit as well
454 as licit entities created or maintained for the purpose of engaging in conduct which constitutes
455 the commission of episodes of activity made unlawful by Title 58, Chapters 37, 37a, 37b, 37c,
456 or 37d, which episodes are not isolated, but have the same or similar purposes, results,
457 participants, victims, methods of commission, or otherwise are interrelated by distinguishing
458 characteristics. Taken together, the episodes shall demonstrate continuing unlawful conduct
459 and be related either to each other or to the enterprise.

460 (e) "Control" means to add, remove, or change the placement of a drug, substance, or
461 immediate precursor under Section 58-37-3.

462 (f) (i) "Controlled substance" means a drug or substance;

463 (A) included in Schedules I, II, III, IV, or V of Section 58-37-4[, and also includes a
464 drug or substance];

465 (B) included in Schedules I, II, III, IV, or V of the federal Controlled Substances Act,
466 Title II, P.L. 91-513[;]; or [any]

467 (C) that is a controlled substance analog.

468 (ii) "Controlled substance" does not include:

469 (A) distilled spirits, wine, or malt beverages, as those terms are defined [or used] in
470 Title 32A, Alcoholic Beverage Control Act[; regarding tobacco or food];

471 (B) any drug intended for lawful use in the diagnosis, cure, mitigation, treatment, or
472 prevention of disease in [man] human or other animals, which contains ephedrine,
473 pseudoephedrine, norpseudoephedrine, or phenylpropanolamine if the drug is lawfully
474 purchased, sold, transferred, or furnished as an over-the-counter medication without
475 prescription; or

476 (C) dietary supplements, vitamins, minerals, herbs, or other similar substances
477 including concentrates or extracts, which;

478 (I) are not otherwise regulated by law[, ~~which~~]; and

479 (II) may contain naturally occurring amounts of chemical or substances listed in this
480 chapter, or in rules adopted pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking
481 Act.

482 (g) (i) "Controlled substance analog" means a substance the chemical structure of
483 which is substantially similar to the chemical structure of a controlled substance listed in
484 Schedules I and II of Section 58-37-4, or in Schedules I and II of the federal Controlled
485 Substances Act, Title II, P.L. 91-513:

486 (A) which has a stimulant, depressant, or hallucinogenic effect on the central nervous
487 system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central
488 nervous system of controlled substances in the schedules set forth in Subsection (1)(f); or

489 (B) which, with respect to a particular individual, is represented or intended to have a
490 stimulant, depressant, or hallucinogenic effect on the central nervous system substantially
491 similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of
492 controlled substances in the schedules set forth in this Subsection (1).

493 (ii) "Controlled substance analog" does not include:

494 (A) a controlled substance currently scheduled in Schedules I through V of Section
495 58-37-4;

496 (B) a substance for which there is an approved new drug application;

497 (C) a substance with respect to which an exemption is in effect for investigational use
498 by a particular person under Section 505 of the Food, Drug, and Cosmetic Act, 21 U.S.C. 355,
499 to the extent the conduct with respect to the substance is permitted by the exemption;

500 (D) any substance to the extent not intended for human consumption before an
501 exemption takes effect with respect to the substance;

502 (E) any drug intended for lawful use in the diagnosis, cure, mitigation, treatment, or
503 prevention of disease in man or other animals, which contains ephedrine, pseudoephedrine,
504 norpseudoephedrine, or phenylpropanolamine if the drug is lawfully purchased, sold,
505 transferred, or furnished as an over-the-counter medication without prescription; or

506 (F) dietary supplements, vitamins, minerals, herbs, or other similar substances
507 including concentrates or extracts, which are not otherwise regulated by law, which may
508 contain naturally occurring amounts of chemical or substances listed in this chapter, or in rules
509 adopted pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

510 (h) "Conviction" means a determination of guilt by verdict, whether jury or bench, or
511 plea, whether guilty or no contest, for any offense proscribed by Title 58, Chapters 37, 37a,
512 37b, 37c, or 37d, or for any offense under the laws of the United States and any other state
513 which, if committed in this state, would be an offense under Title 58, Chapters 37, 37a, 37b,
514 37c, or 37d.

515 (i) "Counterfeit substance" means:

516 (i) any substance or container or labeling of any substance that without authorization
517 bears the trademark, trade name, or other identifying mark, imprint, number, device, or any
518 likeness of them, of a manufacturer, distributor, or dispenser other than the person or persons
519 who in fact manufactured, distributed, or dispensed the substance which falsely purports to be a
520 controlled substance distributed by, any other manufacturer, distributor, or dispenser; or

521 (ii) any substance that is represented to be a controlled substance.

522 (j) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a
523 controlled substance or a listed chemical, whether or not an agency relationship exists.

524 (k) "Department" means the Department of Commerce.

525 (l) "Depressant or stimulant substance" means:

526 (i) a drug which contains any quantity of barbituric acid or any of the salts of barbituric
527 acid;

528 (ii) a drug which contains any quantity of:

529 (A) amphetamine or any of its optical isomers;

530 (B) any salt of amphetamine or any salt of an optical isomer of amphetamine; or

531 (C) any substance which the Secretary of Health and Human Services or the Attorney
532 General of the United States after investigation has found and by regulation designated
533 habit-forming because of its stimulant effect on the central nervous system;

534 (iii) lysergic acid diethylamide; or

535 (iv) any drug which contains any quantity of a substance which the Secretary of Health
536 and Human Services or the Attorney General of the United States after investigation has found
537 to have, and by regulation designated as having, a potential for abuse because of its depressant
538 or stimulant effect on the central nervous system or its hallucinogenic effect.

539 (m) "Dispense" means the delivery of a controlled substance by a pharmacist to an
540 ultimate user pursuant to the lawful order or prescription of a practitioner, and includes
541 distributing to, leaving with, giving away, or disposing of that substance as well as the
542 packaging, labeling, or compounding necessary to prepare the substance for delivery.

543 (n) "Dispenser" means a pharmacist who dispenses a controlled substance.

544 (o) "Distribute" means to deliver other than by administering or dispensing a controlled
545 substance or a listed chemical.

546 (p) "Distributor" means a person who distributes controlled substances.

547 (q) "Division" means the Division of Occupational and Professional Licensing created
548 in Section 58-1-103.

549 (r) (i) "Drug" means:

550 ~~[(i) articles recognized in the official United States Pharmacopoeia, Official~~
551 ~~Homeopathic Pharmacopoeia of the United States, or Official National Formulary, or any~~
552 ~~supplement to any of them;]~~

553 ~~[(ii) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention~~
554 ~~of disease in man or other animals;]~~

555 ~~[(iii) articles, other than food, intended to affect the structure or function of man or~~
556 ~~other animals; and]~~

557 ~~[(iv) articles intended for use as a component of any articles specified in Subsection~~
558 ~~(1)(r)(i), (ii), or (iii); but does not include devices or their components, parts, or accessories.]~~

559 (A) a substance recognized in the official United States Pharmacopoeia, Official
560 Homeopathic Pharmacopoeia of the United States, or Official National Formulary, or any
561 supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or

562 prevention of disease in humans or animals;

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

565 (C) a substance other than food intended to affect the structure or any function of the
566 body of humans or other animals; and

567 (D) substances intended for use as a component of any substance specified in
568 Subsections (1)(r)(i)(A), (B), (C), and (D).

569 (ii) "Drug" does not include dietary supplements.

570 (s) "Drug dependent person" means any individual who unlawfully and habitually uses
571 any controlled substance to endanger the public morals, health, safety, or welfare, or who is so
572 dependent upon the use of controlled substances as to have lost the power of self-control with
573 reference to the individual's dependency.

574 (t) "Food" means:

575 (i) any nutrient or substance of plant, mineral, or animal origin other than a drug as
576 specified in this chapter, and normally ingested by human beings; and

577 (ii) foods for special dietary uses as exist by reason of a physical, physiological,
578 pathological, or other condition including but not limited to the conditions of disease,
579 convalescence, pregnancy, lactation, allergy, hypersensitivity to food, underweight, and
580 overweight; uses for supplying a particular dietary need which exist by reason of age including
581 but not limited to the ages of infancy and childbirth, and also uses for supplementing and for
582 fortifying the ordinary or unusual diet with any vitamin, mineral, or other dietary property for
583 use of a food. Any particular use of a food is a special dietary use regardless of the nutritional
584 purposes.

585 (u) "Immediate precursor" means a substance which the Attorney General of the United
586 States has found to be, and by regulation designated as being, the principal compound used or
587 produced primarily for use in the manufacture of a controlled substance, or which is an
588 immediate chemical intermediary used or likely to be used in the manufacture of a controlled
589 substance, the control of which is necessary to prevent, curtail, or limit the manufacture of the

590 controlled substance.

591 (v) "Indian" means a member of an Indian tribe.

592 (w) "Indian religion" means any religion:

593 (i) the origin and interpretation of which is from within a traditional Indian culture or
594 community; and

595 (ii) which is practiced by Indians.

596 (x) "Indian tribe" means any tribe, band, nation, pueblo, or other organized group or
597 community of Indians, including any Alaska Native village, which is legally recognized as
598 eligible for and is consistent with the special programs, services, and entitlements provided by
599 the United States to Indians because of their status as Indians.

600 (y) "Manufacture" means the production, preparation, propagation, compounding, or
601 processing of a controlled substance, either directly or indirectly by extraction from substances
602 of natural origin, or independently by means of chemical synthesis or by a combination of
603 extraction and chemical synthesis.

604 (z) "Manufacturer" includes any person who packages, repackages, or labels any
605 container of any controlled substance, except pharmacists who dispense or compound
606 prescription orders for delivery to the ultimate consumer.

607 (aa) "Marijuana" means all species of the genus cannabis and all parts of the genus,
608 whether growing or not; the seeds of it; the resin extracted from any part of the plant; and every
609 compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or
610 resin. The term does not include the mature stalks of the plant, fiber produced from the stalks,
611 oil or cake made from the seeds of the plant, any other compound, manufacture, salt,
612 derivative, mixture, or preparation of the mature stalks, except the resin extracted from them,
613 fiber, oil or cake, or the sterilized seed of the plant which is incapable of germination. Any
614 synthetic equivalents of the substances contained in the plant cannabis sativa or any other
615 species of the genus cannabis which are chemically indistinguishable and pharmacologically
616 active are also included.

617 (bb) "Money" means officially issued coin and currency of the United States or any

618 foreign country.

619 (cc) "Narcotic drug" means any of the following, whether produced directly or
620 indirectly by extraction from substances of vegetable origin, or independently by means of
621 chemical synthesis, or by a combination of extraction and chemical synthesis:

622 (i) opium, coca leaves, and opiates;

623 (ii) a compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or
624 opiates;

625 (iii) opium poppy and poppy straw; or

626 (iv) a substance, and any compound, manufacture, salt, derivative, or preparation of the
627 substance, which is chemically identical with any of the substances referred to in Subsection
628 (1)(cc)(i), (ii), or (iii), except narcotic drug does not include decocainized coca leaves or
629 extracts of coca leaves which do not contain cocaine or ecgonine.

630 (dd) "Negotiable instrument" means documents, containing an unconditional promise
631 to pay a sum of money, which are legally transferable to another party by endorsement or
632 delivery.

633 (ee) "Opiate" means any drug or other substance having an addiction-forming or
634 addiction-sustaining liability similar to morphine or being capable of conversion into a drug
635 having addiction-forming or addiction-sustaining liability.

636 (ff) "Opium poppy" means the plant of the species *papaver somniferum* L., except the
637 seeds of the plant.

638 (gg) "Person" means any corporation, association, partnership, trust, other institution or
639 entity or one or more individuals.

640 (hh) "Poppy straw" means all parts, except the seeds, of the opium poppy, after
641 mowing.

642 (ii) "Possession" or "use" means the joint or individual ownership, control, occupancy,
643 holding, retaining, belonging, maintaining, or the application, inhalation, swallowing, injection,
644 or consumption, as distinguished from distribution, of controlled substances and includes
645 individual, joint, or group possession or use of controlled substances. For a person to be a

646 possessor or user of a controlled substance, it is not required that the person be shown to have
647 individually possessed, used, or controlled the substance, but it is sufficient if it is shown that
648 the person jointly participated with one or more persons in the use, possession, or control of
649 any substances with knowledge that the activity was occurring, or the controlled substance is
650 found in a place or under circumstances indicating that the person had the ability and the intent
651 to exercise dominion and control over it.

652 (jj) "Practitioner" means a physician, dentist, naturopathic physician, veterinarian,
653 pharmacist, scientific investigator, pharmacy, hospital, or other person licensed, registered, or
654 otherwise permitted to distribute, dispense, conduct research with respect to, administer, or use
655 in teaching or chemical analysis a controlled substance in the course of professional practice or
656 research in this state.

657 (kk) "Prescribe" means to issue a prescription;

658 (i) orally or in writing[-]; or

659 (ii) by telephone, facsimile transmission, computer, or other electronic means of
660 communication as defined by division rule.

661 (ll) "Prescription" means an order issued;

662 (i) by a licensed practitioner, in the course of that practitioner's professional practice[-]
663 or by collaborative pharmacy practice agreement; and

664 (ii) for a controlled substance[-] or other prescription drug[-] or device [~~which it~~
665 ~~dispenses or administers]~~ for use by a patient or an animal. [~~The order may be issued by word~~
666 ~~of mouth, written document, telephone, facsimile transmission, computer, or other electronic~~
667 ~~means of communication as defined by rule.]~~

668 (mm) "Production" means the manufacture, planting, cultivation, growing, or
669 harvesting of a controlled substance.

670 (nn) "Securities" means any stocks, bonds, notes, or other evidences of debt or of
671 property.

672 (oo) "State" means the state of Utah.

673 (pp) "Ultimate user" means any person who lawfully possesses a controlled substance

674 for the person's own use, for the use of a member of the person's household, or for
675 administration to an animal owned by the person or a member of the person's household.

676 (2) If a term used in this chapter is not defined, the definition and terms of Title 76,
677 Utah Criminal Code, shall apply.

678 Section 5. Section **58-67-102** is amended to read:

679 **58-67-102. Definitions.**

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

681 (1) "ACGME" means the Accreditation Council for Graduate Medical Education of the
682 American Medical Association.

683 (2) "Administrative penalty" means a monetary fine imposed by the division for acts or
684 omissions determined to constitute unprofessional or unlawful conduct, as a result of an
685 adjudicative proceeding conducted in accordance with Title 63G, Chapter 4, Administrative
686 Procedures Act.

687 (3) "Board" means the Physicians Licensing Board created in Section 58-67-201.

688 (4) "Diagnose" means:

689 (a) to examine in any manner another person, parts of a person's body, substances,
690 fluids, or materials excreted, taken, or removed from a person's body, or produced by a person's
691 body, to determine the source, nature, kind, or extent of a disease or other physical or mental
692 condition;

693 (b) to attempt to conduct an examination or determination described under Subsection
694 (4)(a);

695 (c) to hold oneself out as making or to represent that one is making an examination or
696 determination as described in Subsection (4)(a); or

697 (d) to make an examination or determination as described in Subsection (4)(a) upon or
698 from information supplied directly or indirectly by another person, whether or not in the
699 presence of the person making or attempting the diagnosis or examination.

700 (5) "LCME" means the Liaison Committee on Medical Education of the American
701 Medical Association.

702 (6) "Medical assistant" means an unlicensed individual working under the direct and
703 immediate supervision of a licensed physician and surgeon and engaged in specific tasks
704 assigned by the licensed physician and surgeon in accordance with the standards and ethics of
705 the profession.

706 (7) "Physician" means both physicians and surgeons licensed under Section 58-67-301,
707 Utah Medical Practice Act, and osteopathic physicians and surgeons licensed under Section
708 58-68-301, Utah Osteopathic Medical Practice Act.

709 (8) "Practice of medicine" means:

710 (a) to diagnose, treat, correct, administer anesthesia, or prescribe for any human
711 disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real
712 or imaginary, or to attempt to do so, by any means or instrumentality, and by an individual in
713 Utah or outside the state upon or for any human within the state, except that conduct described
714 in this Subsection (8)(a) that is performed by a person legally and in accordance with a license
715 issued under another chapter of this title does not constitute the practice of medicine;

716 (b) when a person not licensed as a physician directs a licensee under this chapter to
717 withhold or alter the health care services that the licensee has ordered, but practice of medicine
718 does not include any conduct under Subsection 58-67-501(2);

719 (c) to maintain an office or place of business for the purpose of doing any of the acts
720 described in Subsection (8)(a) whether or not for compensation; or

721 (d) to use, in the conduct of any occupation or profession pertaining to the diagnosis or
722 treatment of human diseases or conditions in any printed material, stationery, letterhead,
723 envelopes, signs, or advertisements, the designation "doctor," "doctor of medicine,"
724 "physician," "surgeon," "physician and surgeon," "Dr.," "M.D.," or any combination of these
725 designations in any manner which might cause a reasonable person to believe the individual
726 using the designation is a licensed physician and surgeon, and if the party using the designation
727 is not a licensed physician and surgeon, the designation must additionally contain the
728 description of the branch of the healing arts for which the person has a license.

729 (9) "Prescription [~~drug or~~] device" means[:] an instrument, apparatus, implement,

730 machine, contrivance, implant, in vitro reagent, or other similar or related article, and any
731 component part or accessory, which is required under federal or state law to be prescribed by a
732 practitioner and dispensed by or through a person or entity licensed under this chapter or
733 exempt from licensure under this chapter.

734 [~~(a) a drug or device which, under federal law, is required to be labeled with either of~~
735 ~~the following statements or their equivalent:]~~

736 [~~(i) "CAUTION: Federal law prohibits dispensing without prescription"; or]~~

737 [~~(ii) "CAUTION: Federal law restricts this drug to use by or on the order of a licensed~~
738 ~~veterinarian"; or]~~

739 [~~(b) a drug or device that is required by any applicable federal or state law or rule to be~~
740 ~~dispensed on prescription only or is restricted to use by practitioners only:]~~

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

743 [~~(10)] (11) "SPEX" means the Special Purpose Examination of the Federation of State~~

744 Medical Boards.

745 [~~(11)] (12) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-67-501.~~

746 [~~(12)] (13) "Unprofessional conduct" is as defined in Sections 58-1-501 and~~

747 58-67-502, and as may be further defined by division rule.

748 Section 6. Section **58-68-102** is amended to read:

749 **58-68-102. Definitions.**

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

751 (1) "ACGME" means the Accreditation Council for Graduate Medical Education of the
752 American Medical Association.

753 (2) "Administrative penalty" means a monetary fine imposed by the division for acts or
754 omissions determined to constitute unprofessional or unlawful conduct, as a result of an
755 adjudicative proceeding conducted in accordance with Title 63G, Chapter 4, Administrative
756 Procedures Act.

757 (3) "AOA" means the American Osteopathic Association.

758 (4) "Board" means the Osteopathic Physicians Licensing Board created in Section
759 58-68-201.

760 (5) "Diagnose" means:

761 (a) to examine in any manner another person, parts of a person's body, substances,
762 fluids, or materials excreted, taken, or removed from a person's body, or produced by a person's
763 body, to determine the source, nature, kind, or extent of a disease or other physical or mental
764 condition;

765 (b) to attempt to conduct an examination or determination described under Subsection
766 (5)(a);

767 (c) to hold oneself out as making or to represent that one is making an examination or
768 determination as described in Subsection (5)(a); or

769 (d) to make an examination or determination as described in Subsection (5)(a) upon or
770 from information supplied directly or indirectly by another person, whether or not in the
771 presence of the person making or attempting the diagnosis or examination.

772 (6) "Medical assistant" means an unlicensed individual working under the direct and
773 immediate supervision of a licensed osteopathic physician and surgeon and engaged in specific
774 tasks assigned by the licensed osteopathic physician and surgeon in accordance with the
775 standards and ethics of the profession.

776 (7) "Physician" means both physicians and surgeons licensed under Section 58-67-301,
777 Utah Medical Practice Act, and osteopathic physicians and surgeons licensed under Section
778 58-68-301, Utah Osteopathic Medical Practice Act.

779 (8) "Practice of osteopathic medicine" means:

780 (a) to diagnose, treat, correct, administer anesthesia, or prescribe for any human
781 disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real
782 or imaginary, or to attempt to do so, by any means or instrumentality, which in whole or in part
783 is based upon emphasis of the importance of the musculoskeletal system and manipulative
784 therapy in the maintenance and restoration of health, by an individual in Utah or outside of the
785 state upon or for any human within the state, except that conduct described in this Subsection

786 (8)(a) that is performed by a person legally and in accordance with a license issued under
787 another chapter of this title does not constitute the practice of medicine;

788 (b) when a person not licensed as a physician directs a licensee under this chapter to
789 withhold or alter the health care services that the licensee has ordered, but practice of medicine
790 does not include any conduct under Subsection 58-68-501(2);

791 (c) to maintain an office or place of business for the purpose of doing any of the acts
792 described in Subsection (8)(a) whether or not for compensation; or

793 (d) to use, in the conduct of any occupation or profession pertaining to the diagnosis or
794 treatment of human diseases or conditions, in any printed material, stationery, letterhead,
795 envelopes, signs, or advertisements, the designation "doctor," "doctor of osteopathic medicine,"
796 "osteopathic physician," "osteopathic surgeon," "osteopathic physician and surgeon," "Dr.,"
797 "D.O.," or any combination of these designations in any manner which might cause a
798 reasonable person to believe the individual using the designation is a licensed osteopathic
799 physician, and if the party using the designation is not a licensed osteopathic physician, the
800 designation must additionally contain the description of the branch of the healing arts for which
801 the person has a license.

802 (9) "Prescription [~~drug or~~ device" means[:] an instrument, apparatus, implement,
803 machine, contrivance, implant, in vitro reagent, or other similar or related article, and any
804 component part or accessory, which is required under federal or state law to be prescribed by a
805 practitioner and dispensed by or through a person or entity licensed under this chapter or
806 exempt from licensure under this chapter.

807 [~~(a) a drug or device which, under federal law, is required to be labeled with either]~~
808 [~~of the following statements or their equivalent:]~~

809 [~~(i) "CAUTION: Federal law prohibits dispensing without prescription"; or]~~

810 [~~(ii) "CAUTION: Federal law restricts this drug to use by or on the order of a licensed~~
811 ~~veterinarian"; or]~~

812 [~~(b) a drug or device that is required by any applicable federal or state law or rule to be~~
813 ~~dispensed on prescription only or is restricted to use by practitioners only.]~~

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

816 ~~[(10)]~~ (11) "SPEX" means the Special Purpose Examination of the Federation of State
817 Medical Boards.

818 ~~[(11)]~~ (12) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-68-501.

819 ~~[(12)]~~ (13) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-68-502
820 and as may be further defined by division rule.

821 Section 7. Section **58-71-102** is amended to read:

822 **58-71-102. Definitions.**

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

824 (1) "Administrative penalty" means a monetary fine imposed by the division for acts or
825 omissions determined to constitute unprofessional or unlawful conduct, as a result of an
826 adjudicative proceeding conducted in accordance with Title 63G, Chapter 4, Administrative
827 Procedures Act.

828 (2) "Acupuncture" has the same definition as in Section 58-72-102.

829 (3) "Board" means the Naturopathic Physicians Licensing Board created in Section
830 58-71-201.

831 (4) "Diagnose" means:

832 (a) to examine in any manner another person, parts of a person's body, substances,
833 fluids, or materials excreted, taken, or removed from a person's body, or produced by a person's
834 body, to determine the source, nature, kind, or extent of a disease or other physical or mental
835 condition;

836 (b) to attempt to conduct an examination or determination described under Subsection
837 (4)(a);

838 (c) to hold oneself out as making or to represent that one is making an examination or
839 determination as described in Subsection (4)(a); or

840 (d) to make an examination or determination as described in Subsection (4)(a) upon or
841 from information supplied directly or indirectly by another person, whether or not in the

842 presence of the person making or attempting the diagnosis or examination.

843 (5) "Local anesthesia" means an agent, whether a natural medicine or prescription drug,
844 which:

845 (a) is applied topically or by injection in superficial tissues associated with the
846 performance of minor office procedures;

847 (b) has the ability to produce loss of sensation at the site of minor office procedures;
848 and

849 (c) does not cause loss of consciousness or produce general sedation.

850 (6) "Medical naturopathic assistant" means an unlicensed individual working under the
851 direct and immediate supervision of a licensed naturopathic physician and engaged in specific
852 tasks assigned by the licensed naturopathic physician in accordance with the standards and
853 ethics of the profession.

854 (7) (a) "Minor office procedures" means:

855 (i) the use of operative, electrical, or other methods for repair and care of superficial
856 lacerations, abrasions, and benign lesions;

857 (ii) removal of foreign bodies located in the superficial tissues, excluding the eye or
858 ear; and

859 (iii) the use of antiseptics and local anesthetics in connection with minor office surgical
860 procedures.

861 (b) "Minor office procedures" does not include:

862 (i) general or spinal anesthesia;

863 (ii) office procedures more complicated or extensive than those set forth in Subsection
864 (7)(a);

865 (iii) procedures involving the eye; or

866 (iv) any office procedure involving tendons, nerves, veins, or arteries.

867 (8) "Natural medicine" means:

868 (a) food, food extracts, dietary supplements as defined by the federal Food, Drug, and
869 Cosmetics Act, all homeopathic remedies, and plant substances that are not designated as

- 870 prescription drugs or controlled substances;
- 871 (b) over-the-counter medications;
- 872 (c) other nonprescription substances, the prescription or administration of which is not
873 otherwise prohibited or restricted under federal or state law;
- 874 (d) prescription drugs:
- 875 (i) that, except as provided in Subsection (8)(e), are not controlled substances as
876 defined in Section 58-37-2;
- 877 (ii) the prescription of which is consistent with the competent practice of naturopathic
878 medicine; and
- 879 (iii) the prescription of which is approved by the division in collaboration with the
880 naturopathic formulary advisory peer committee; and
- 881 (e) testosterone, if the testosterone is:
- 882 (i) bio-identical;
- 883 (ii) designed to be:
- 884 (A) administered topically, for transdermal absorption; or
- 885 (B) absorbed across the mucosal membranes of the mouth; and
- 886 (iii) prescribed or administered, in accordance with the requirements of federal and
887 state law, solely for the purpose of treating a patient with a low testosterone level in order to
888 restore the patient to a normal testosterone level.
- 889 (9) (a) "Naturopathic childbirth" means uncomplicated natural childbirth assisted by a
890 naturopathic physician, and includes the use of:
- 891 (i) natural medicines; and
- 892 (ii) uncomplicated episiotomy.
- 893 (b) "Naturopathic childbirth" does not include the use of:
- 894 (i) forceps delivery;
- 895 (ii) general or spinal anesthesia;
- 896 (iii) caesarean section delivery; or
- 897 (iv) induced labor or abortion.

- 898 (10) "Naturopathic mobilization therapy":
- 899 (a) means manually administering mechanical treatment of body structures or tissues
- 900 for the purpose of restoring normal physiological function to the body by normalizing and
- 901 balancing the musculoskeletal system of the body;
- 902 (b) does not mean manipulation or adjustment of the joints of the human body beyond
- 903 the elastic barrier; and
- 904 (c) does not include manipulation as defined in Title 58, Chapter 73, Chiropractic
- 905 Physician Practice Act.
- 906 (11) "Naturopathic physical medicine" means the use of the physical agents of air,
- 907 water, heat, cold, sound, light, and electromagnetic nonionizing radiation, and the physical
- 908 modalities of electrotherapy, biofeedback, acupuncture, diathermy, ultraviolet light, ultrasound,
- 909 hydrotherapy, naturopathic mobilization therapy, and exercise. Naturopathic medicine does not
- 910 include the practice of physical therapy or physical rehabilitation.
- 911 (12) "Practice of naturopathic medicine" means:
- 912 (a) a system of primary health care for the prevention, diagnosis, and treatment of
- 913 human health conditions, injuries, and diseases that uses education, natural medicines, and
- 914 natural therapies, to support and stimulate the patient's intrinsic self-healing processes:
- 915 (i) using naturopathic childbirth, but only if:
- 916 (A) the licensee meets standards of the American College of Naturopathic
- 917 Obstetricians (ACNO) or its successor as determined by the division in collaboration with the
- 918 board; and
- 919 (B) the licensee follows a written plan for naturopathic physicians practicing
- 920 naturopathic childbirth approved by the division in collaboration with the board, which
- 921 includes entering into an agreement with a consulting physician and surgeon or osteopathic
- 922 physician, in cases where the scope of practice of naturopathic childbirth may be exceeded and
- 923 specialty care and delivery is indicated, detailing the guidelines by which the naturopathic
- 924 physician will:
- 925 (I) refer patients to the consulting physician; and

- 926 (II) consult with the consulting physician;
- 927 (ii) using naturopathic mobilization therapy;
- 928 (iii) using naturopathic physical medicine;
- 929 (iv) using minor office procedures;
- 930 (v) prescribing or administering natural medicine;
- 931 (vi) prescribing medical equipment and devices, diagnosing by the use of medical
- 932 equipment and devices, and administering therapy or treatment by the use of medical devices
- 933 necessary and consistent with the competent practice of naturopathic medicine;
- 934 (vii) prescribing barrier devices for contraception;
- 935 (viii) using dietary therapy;
- 936 (ix) taking and using diagnostic x-rays, electrocardiograms, ultrasound, and
- 937 physiological function tests;
- 938 (x) taking of body fluids for clinical laboratory tests and using the results of the tests in
- 939 diagnosis;
- 940 (xi) taking of a history from and conducting of a physical examination upon a human
- 941 patient; and
- 942 (xii) prescribing and administering natural medicines and medical devices, except a
- 943 naturopathic physician may only administer:
- 944 (A) a prescription drug, as defined in Section 58-17b-102, in accordance with
- 945 Subsection (8)(d); and
- 946 (B) local anesthesia that is not a controlled substance, and only in the performance of
- 947 minor office procedures;
- 948 (b) to maintain an office or place of business for the purpose of doing any of the acts
- 949 described in Subsection (12)(a), whether or not for compensation; or
- 950 (c) to use, in the conduct of any occupation or profession pertaining to the diagnosis or
- 951 treatment of human diseases or conditions, in any printed material, stationery, letterhead,
- 952 envelopes, signs, or advertisements, the designation "naturopathic physician," "naturopathic
- 953 doctor," "naturopath," "doctor of naturopathic medicine," "doctor of naturopathy,"

954 "naturopathic medical doctor," "naturopathic medicine," "naturopathic health care,"
955 "naturopathy," "N.D.," "N.M.D.," or any combination of these designations in any manner that
956 might cause a reasonable person to believe the individual using the designation is a licensed
957 naturopathic physician.

958 (13) "Prescribe" means to issue a prescription:

959 (a) orally or in writing; or

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

962 ~~[(13)]~~ (14) "Prescription [drug-or] device" means[:] an instrument, apparatus,
963 implement, machine, contrivance, implant, in vitro reagent, or other similar or related article,
964 and any component part or accessory, which is required under federal or state law to be
965 prescribed by a practitioner and dispensed by or through a person or entity licensed under this
966 chapter or exempt from licensure under this chapter.

967 ~~[(a) a drug or device which, under federal law, is required to be labeled with either of~~
968 ~~the following statements or their equivalent:]~~

969 ~~[(i) "CAUTION: Federal law prohibits dispensing without prescription"; or]~~

970 ~~[(ii) "CAUTION: Federal law restricts this drug to use by or on the order of a licensed~~
971 ~~veterinarian"; or]~~

972 ~~[(b) a drug or device that is required by any applicable federal or state law or rule to be~~
973 ~~dispensed on prescription only or is restricted to use by practitioners only.]~~

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

976 ~~[(14)]~~ (16) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-71-501.

977 ~~[(15)]~~ (17) "Unprofessional conduct" is as defined in Sections 58-1-501 and
978 58-71-502, and as may be further defined by division rule.