Senator Evan J. Vickers proposes the following substitute bill:

	PHARMACY PRACTICE ACT AMENDMENTS
	2024 GENERAL SESSION
	STATE OF UTAH
	Chief Sponsor: Evan J. Vickers
	House Sponsor: Steve Eliason
LONG 7	TITLE
General	Description:
Т	his bill amends and enacts provisions related to pharmacists and pharmacies.
Highligh	ted Provisions:
Т	his bill:
•	makes technical corrections;
•	defines "written communication";
•	for a pharmacy other than a class D pharmacy, requires the pharmacist-in-charge,
and not e	each manager, to submit fingerprint cards and consent to a fingerprint
backgrou	ind check;
►	grants limited rulemaking authority to the Division of Professional Licensing to
prescribe	a method by which a pharmacy may update the address registered to a
pharmac	y's license;
Þ	under certain conditions, allows a hospital pharmacy to dispense a limited supply of
a prescri	ption drug to an individual who is no longer a patient in the hospital;
►	modifies provisions governing patient counseling;
►	allows for the delivery of medication guides and medication package inserts via
written c	ommunication, as defined;
Þ	permits a pharmacy to update the address registered to a pharmacy's license, if there

26	has been no change in the underlying ownership or control of the pharmacy;
27	 modifies requirements related to pharmacy audits; and
28	 applies the provisions of Title 58, Chapter 88, Part 2, Dispensing Practice, to a
.9	physician who dispenses a prescription drug or device to a patient for the patient's
0	immediate needs, subject to conditions.
1	Money Appropriated in this Bill:
52	None
3	Other Special Clauses:
4	This bill provides a coordination clause.
5	Utah Code Sections Affected:
6	AMENDS:
7	58-17b-102, as last amended by Laws of Utah 2023, Chapters 223, 328
8	58-17b-306, as last amended by Laws of Utah 2023, Chapter 223
9	58-17b-603, as enacted by Laws of Utah 2004, Chapter 280
0	58-17b-610.6, as last amended by Laws of Utah 2022, Chapter 465
1	58-17b-613, as last amended by Laws of Utah 2015, Chapter 336
-2	58-17b-614, as last amended by Laws of Utah 2020, Chapter 339
3	58-17b-622, as last amended by Laws of Utah 2023, Chapter 329
4	58-88-202, as enacted by Laws of Utah 2022, Chapter 353
5	REPEALS:
6	58-17b-610.5, as last amended by Laws of Utah 2020, Chapter 81
7	Utah Code Sections Affected By Coordination Clause:
8	58-17b-622, as last amended by Laws of Utah 2023, Chapter 329
.9 0	Be it enacted by the Legislature of the state of Utah:
1	Section 1. Section 58-17b-102 is amended to read:
2	58-17b-102. Definitions.
3	In addition to the definitions in Section 58-1-102, as used in this chapter:
4	(1) "Administering" means:
5	(a) the direct application of a prescription drug or device, whether by injection,

57 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.

62 (2) "Adulterated drug or device" means a drug or device considered adulterated under
63 21 U.S.C. Sec. 351 (2003).

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

66 (b) "Analytical laboratory" does not include a laboratory possessing prescription drugs 67 used as standards and controls in performing drug monitoring or drug screening analysis if the 68 prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid 69 components, organic solvents, or inorganic buffers at a concentration not exceeding one 70 milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic 71 use.

(4) "Animal euthanasia agency" means an agency performing euthanasia on animals bythe 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
all transaction information.

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

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

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



(9) "Centralized prescription processing" means the processing by a pharmacy of a

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88 request from another pharmacy to fill or refill a prescription drug order or to perform 89 processing functions such as dispensing, drug utilization review, claims adjudication, refill 90 authorizations, and therapeutic interventions. (10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a 91 92 retail pharmacy to compound or dispense a drug or dispense a device to the public under a 93 prescription order. 94 (11) "Class B pharmacy": 95 (a) means a pharmacy located in Utah: 96 (i) that is authorized to provide pharmaceutical care for patients in an institutional 97 setting; and 98 (ii) whose primary purpose is to provide a physical environment for patients to obtain 99 health care services; and 100 (b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and (ii) pharmaceutical administration and sterile product preparation facilities. 101 (12) "Class C pharmacy" means a pharmacy that engages in the manufacture. 102 103 production, wholesale, or distribution of drugs or devices in Utah. (13) "Class D pharmacy" means a nonresident pharmacy. 104 (14) "Class E pharmacy" means all other pharmacies. 105 106 (15) (a) "Closed-door pharmacy" means a pharmacy that: 107 (i) provides pharmaceutical care to a defined and exclusive group of patients who have 108 access to the services of the pharmacy because they are treated by or have an affiliation with a specific entity, including a health maintenance organization or an infusion company; or 109 110 (ii) engages exclusively in the practice of telepharmacy and does not serve walk-in 111 retail customers. 112 (b) "Closed-door pharmacy" does not include a hospital pharmacy, a retailer of goods 113 to the general public, or the office of a practitioner. 114 (16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or 115 more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or 116 more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical 117 care functions authorized by the practitioner or practitioners under certain specified conditions 118 or limitations.

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119	(17) "Collaborative pharmacy practice agreement" means a written and signed
120	agreement between one or more pharmacists and one or more practitioners that provides for
121	collaborative pharmacy practice for the purpose of drug therapy management of patients and
122	prevention of disease of human subjects.
123	(18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or
124	labeling of a limited quantity drug, sterile product, or device:
125	(i) as the result of a practitioner's prescription order or initiative based on the
126	practitioner, patient, or pharmacist relationship in the course of professional practice;
127	(ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and
128	not for sale or dispensing; or
129	(iii) in anticipation of prescription drug orders based on routine, regularly observed
130	prescribing patterns.
131	(b) "Compounding" does not include:
132	(i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to
133	another pharmacist or pharmaceutical facility;
134	(ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a
135	dosage form which is regularly and commonly available from a manufacturer in quantities and
136	strengths prescribed by a practitioner; or
137	(iii) the preparation of a prescription drug, sterile product, or device which has been
138	withdrawn from the market for safety reasons.
139	(19) "Confidential information" has the same meaning as "protected health
140	information" under the Standards for Privacy of Individually Identifiable Health Information,
141	45 C.F.R. Parts 160 and 164.
142	(20) "Controlled substance" means the same as that term is defined in Section 58-37-2.
143	(21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
144	417, Sec. 3a(ff) which is incorporated by reference.
145	(22) "Dispense" means the interpretation, evaluation, and implementation of a
146	prescription drug order or device or nonprescription drug or device under a lawful order of a
147	practitioner in a suitable container appropriately labeled for subsequent administration to or use
148	by a patient, research subject, or an animal.
149	(23) "Dispensing medical practitioner" means an individual who is:

150	(a) currently licensed as:
151	(i) a physician and surgeon under Chapter 67, Utah Medical Practice Act;
152	(ii) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical
153	Practice Act;
154	(iii) a physician assistant under Chapter 70a, Utah Physician Assistant Act;
155	(iv) a nurse practitioner under Chapter 31b, Nurse Practice Act; or
156	(v) an optometrist under Chapter 16a, Utah Optometry Practice Act, if the optometrist
157	is acting within the scope of practice for an optometrist; and
158	(b) licensed by the division under the Pharmacy Practice Act to engage in the practice
159	of a dispensing medical practitioner.
160	(24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy
161	located within a licensed dispensing medical practitioner's place of practice.
162	(25) "Distribute" means to deliver a drug or device other than by administering or
163	dispensing.
164	(26) (a) "Drug" means:
165	(i) a substance recognized in the official United States Pharmacopoeia, official
166	Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any
167	supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or
168	prevention of disease in humans or animals;
169	(ii) a substance that is required by any applicable federal or state law or rule to be
170	dispensed by prescription only or is restricted to administration by practitioners only;
171	(iii) a substance other than food intended to affect the structure or any function of the
172	body of humans or other animals; and
173	(iv) substances intended for use as a component of any substance specified in
174	Subsections [(26)(a)(i), (ii), (iii), and (iv)] (26)(a)(i) through (iv).
175	(b) "Drug" does not include dietary supplements.
176	(27) "Drug regimen review" includes the following activities:
177	(a) evaluation of the prescription drug order and patient record for:
178	(i) known allergies;
179	(ii) rational therapy-contraindications;
180	(iii) reasonable dose and route of administration; and

181 (iv) reasonable directions for use;

(b) evaluation of the prescription drug order and patient record for duplication oftherapy;

(c) evaluation of the prescription drug order and patient record for the followinginteractions:

186 (i) drug-drug;

187 (ii) drug-food;

188 (iii) drug-disease; and

189 (iv) adverse drug reactions; and

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

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

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

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

(31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to
inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
and Human Services under Title 26B, Chapter 2, Part 2, Health Care Facility Licensing and
Inspection.

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

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

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

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212	(35) (a) "Manufacturing" means:
213	(i) the production, preparation, propagation, conversion, or processing of a drug or
214	device, either directly or indirectly, by extraction from substances of natural origin or
215	independently by means of chemical or biological synthesis, or by a combination of extraction
216	and chemical synthesis, and includes any packaging or repackaging of the substance or labeling
217	or relabeling of its container; and
218	(ii) the promotion and marketing of such drugs or devices.
219	(b) "Manufacturing" includes the preparation and promotion of commercially available
220	products from bulk compounds for resale by pharmacies, practitioners, or other persons.
221	(c) "Manufacturing" does not include the preparation or compounding of a drug by a
222	pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation,
223	compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical
224	analysis.
225	(36) "Medical order" means a lawful order of a practitioner which may include a
226	prescription drug order.
227	(37) "Medication profile" or "profile" means a record system maintained as to drugs or
228	devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze
229	the profile to provide pharmaceutical care.
230	(38) "Misbranded drug or device" means a drug or device considered misbranded under
231	21 U.S.C. Sec. 352 (2003).
232	(39) (a) "Nonprescription drug" means a drug which:
233	(i) may be sold without a prescription; and
234	(ii) is labeled for use by the consumer in accordance with federal law.
235	(b) "Nonprescription drug" includes homeopathic remedies.
236	(40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a
237	person in Utah.
238	(41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.
239	(42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located
240	outside the state that is licensed and in good standing in another state, that:
241	(a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in
242	this state pursuant to a lawfully issued prescription;

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243	(b) provides information to a patient in this state on drugs or devices which may
244	include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses;
245	or
246	(c) counsels pharmacy patients residing in this state concerning adverse and therapeutic
247	effects of drugs.
248	(43) "Patient counseling" means the written and oral communication by the pharmacist
249	or pharmacy intern of information, to the patient or caregiver, in order to ensure proper use of
250	drugs, devices, and dietary supplements.
251	(44) "Pharmaceutical administration facility" means a facility, agency, or institution in
252	which:
253	(a) prescription drugs or devices are held, stored, or are otherwise under the control of
254	the facility or agency for administration to patients of that facility or agency;
255	(b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist
256	or pharmacy intern with whom the facility has established a prescription drug supervising
257	relationship under which the pharmacist or pharmacy intern provides counseling to the facility
258	or agency staff as required, and oversees drug control, accounting, and destruction; and
259	(c) prescription drugs are professionally administered in accordance with the order of a
260	practitioner by an employee or agent of the facility or agency.
261	(45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a
262	prescribing practitioner, and in accordance with division rule:
263	(i) designing, implementing, and monitoring a therapeutic drug plan intended to
264	achieve favorable outcomes related to a specific patient for the purpose of curing or preventing
265	the patient's disease;
266	(ii) eliminating or reducing a patient's symptoms; or
267	(iii) arresting or slowing a disease process.
268	(b) "Pharmaceutical care" does not include prescribing of drugs without consent of a
269	prescribing practitioner.
270	(46) "Pharmaceutical facility" means a business engaged in the dispensing, delivering,
271	distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this
272	state.
273	(47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility

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274 engaged in the business of wholesale vending or selling of a prescription drug or device to 275 other than a consumer or user of the prescription drug or device that the pharmaceutical facility 276 has not produced, manufactured, compounded, or dispensed. 277 (b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical 278 facility carrying out the following business activities: 279 (i) intracompany sales; 280 (ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, 281 purchase, or trade a prescription drug or device, if the activity is carried out between one or 282 more of the following entities under common ownership or common administrative control, as 283 defined by division rule: 284 (A) hospitals; 285 (B) pharmacies; 286 (C) chain pharmacy warehouses, as defined by division rule; or 287 (D) other health care entities, as defined by division rule; 288 (iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, 289 purchase, or trade a prescription drug or device, for emergency medical reasons, including 290 supplying another pharmaceutical facility with a limited quantity of a drug, if: 291 (A) the facility is unable to obtain the drug through a normal distribution channel in 292 sufficient time to eliminate the risk of harm to a patient that would result from a delay in 293 obtaining the drug; and 294 (B) the quantity of the drug does not exceed an amount reasonably required for 295 immediate dispensing to eliminate the risk of harm; 296 (iv) the distribution of a prescription drug or device as a sample by representatives of a 297 manufacturer; and 298 (v) the distribution of prescription drugs, if: 299 (A) the facility's total distribution-related sales of prescription drugs does not exceed 300 5% of the facility's total prescription drug sales; and 301 (B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11. 302 (48) "Pharmacist" means an individual licensed by this state to engage in the practice 303 of pharmacy. (49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing 304

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305 who accepts responsibility for the operation of a pharmacy in conformance with all laws and 306 rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally 307 in full and actual charge of the pharmacy and all personnel. 308 (50) "Pharmacist preceptor" means a licensed pharmacist in good standing with one or 309 more years of licensed experience. The preceptor serves as a teacher, example of professional 310 conduct, and supervisor of interns in the professional practice of pharmacy. (51) "Pharmacy" means any place where: 311 312 (a) drugs are dispensed: 313 (b) pharmaceutical care is provided; 314 (c) drugs are processed or handled for eventual use by a patient; or 315 (d) drugs are used for the purpose of analysis or research. 316 (52) "Pharmacy benefits manager or coordinator" means a person or entity that 317 provides a pharmacy benefits management service as defined in Section 31A-46-102 on behalf 318 of a self-insured employer, insurance company, health maintenance organization, or other plan 319 sponsor, as defined by rule. 320 (53) "Pharmacy intern" means an individual licensed by this state to engage in practice 321 as a pharmacy intern. 322 (54) "Pharmacy manager" means: 323 (a) a pharmacist-in-charge; 324 (b) a licensed pharmacist designated by a licensed pharmacy to consult on the 325 pharmacy's administration; 326 (c) an individual who manages the facility in which a licensed pharmacy is located; 327 (d) an individual who oversees the operations of a licensed pharmacy; 328 (e) an immediate supervisor of an individual described in Subsections (54)(a) through 329 (d); or 330 (f) another operations or site manager of a licensed pharmacy. 331 (55) "Pharmacy technician training program" means an approved technician training 332 program providing education for pharmacy technicians. 333 (56) (a) "Practice as a dispensing medical practitioner" means the practice of pharmacy, 334 specifically relating to the dispensing of a prescription drug in accordance with Part 8, 335 Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, and

336	division rule adopted after consultation with the Board of pharmacy and the governing boards
337	of the practitioners described in Subsection (23)(a).
338	(b) "Practice as a dispensing medical practitioner" does not include:
339	(i) using a vending type of dispenser as defined by the division by administrative rule;
340	or
341	(ii) except as permitted by Section 58-17b-805, dispensing of a controlled substance as
342	defined in Section 58-37-2.
343	(57) "Practice as a licensed pharmacy technician" means engaging in practice as a
344	pharmacy technician under the general supervision of a licensed pharmacist and in accordance
345	with a scope of practice defined by division rule made in collaboration with the board.
346	(58) "Practice of pharmacy" includes the following:
347	(a) providing pharmaceutical care;
348	(b) collaborative pharmacy practice in accordance with a collaborative pharmacy
349	practice agreement;
350	(c) compounding, packaging, labeling, dispensing, administering, and the coincident
351	distribution of prescription drugs or devices, provided that the administration of a prescription
352	drug or device is:
353	(i) pursuant to a lawful order of a practitioner when one is required by law; and
354	(ii) in accordance with written guidelines or protocols:
355	(A) established by the licensed facility in which the prescription drug or device is to be
356	administered on an inpatient basis; or
357	(B) approved by the division, in collaboration with the board and, when appropriate,
358	the Physicians Licensing Board, created in Section 58-67-201, if the prescription drug or device
359	is to be administered on an outpatient basis solely by a licensed pharmacist;
360	(d) participating in drug utilization review;
361	(e) ensuring proper and safe storage of drugs and devices;
362	(f) maintaining records of drugs and devices in accordance with state and federal law
363	and the standards and ethics of the profession;
364	(g) providing information on drugs or devices, which may include advice relating to
365	therapeutic values, potential hazards, and uses;
366	(h) providing drug product equivalents;

367	(i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
368	technicians;
369	(j) providing patient counseling, including adverse and therapeutic effects of drugs;
370	(k) providing emergency refills as defined by rule;
371	(1) telepharmacy;
372	(m) formulary management intervention;
373	(n) prescribing and dispensing a self-administered hormonal contraceptive in
374	accordance with Title 26B, Chapter 4, Part 5, Treatment Access; and
375	(o) issuing a prescription in accordance with Section 58-17b-627.
376	(59) "Practice of telepharmacy" means the practice of pharmacy through the use of
377	telecommunications and information technologies.
378	(60) "Practice of telepharmacy across state lines" means the practice of pharmacy
379	through the use of telecommunications and information technologies that occurs when the
380	patient is physically located within one jurisdiction and the pharmacist is located in another
381	jurisdiction.
382	(61) "Practitioner" means an individual currently licensed, registered, or otherwise
383	authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of
384	professional practice.
385	(62) "Prescribe" means to issue a prescription:
386	(a) orally or in writing; or
387	(b) by telephone, facsimile transmission, computer, or other electronic means of
388	communication as defined by division rule.
389	(63) "Prescription" means an order issued:
390	(a) by a licensed practitioner in the course of that practitioner's professional practice or
391	by collaborative pharmacy practice agreement; and
392	(b) for a controlled substance or other prescription drug or device for use by a patient
393	or an animal.
394	(64) "Prescription device" means an instrument, apparatus, implement, machine,
395	contrivance, implant, in vitro reagent, or other similar or related article, and any component
396	part or accessory, which is required under federal or state law to be prescribed by a practitioner
397	and dispensed by or through a person or entity licensed under this chapter or exempt from

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398 licensure under this chapter. 399 (65) "Prescription drug" means a drug that is required by federal or state law or rule to 400 be dispensed only by prescription or is restricted to administration only by practitioners. 401 (66) "Repackage": 402 (a) means changing the container, wrapper, or labeling to further the distribution of a 403 prescription drug; and 404 (b) does not include: 405 (i) Subsection (66)(a) when completed by the pharmacist responsible for dispensing the 406 product to a patient; or 407 (ii) changing or altering a label as necessary for a dispensing practitioner under Part 8, 408 Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, for 409 dispensing a product to a patient. 410 (67) "Research using pharmaceuticals" means research: 411 (a) conducted in a research facility, as defined by division rule, that is associated with a 412 university or college in the state accredited by the Northwest Commission on Colleges and 413 Universities; 414 (b) requiring the use of a controlled substance, prescription drug, or prescription 415 device; 416 (c) that uses the controlled substance, prescription drug, or prescription device in 417 accordance with standard research protocols and techniques, including, if required, those 418 approved by an institutional review committee; and 419 (d) that includes any documentation required for the conduct of the research and the 420 handling of the controlled substance, prescription drug, or prescription device. 421 (68) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs 422 and devices to the general public. 423 (69) (a) "Self-administered hormonal contraceptive" means a self-administered 424 hormonal contraceptive that is approved by the United States Food and Drug Administration to 425 prevent pregnancy. 426 (b) "Self-administered hormonal contraceptive" includes an oral hormonal 427 contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch. 428 (c) "Self-administered hormonal contraceptive" does not include any drug intended to

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429	induce an abortion, as that term is defined in Section 76-7-301.
430	(70) "Self-audit" means an internal evaluation of a pharmacy to determine compliance
431	with this chapter.
432	(71) "Supervising pharmacist" means a pharmacist who is overseeing the operation of
433	the pharmacy during a given day or shift.
434	(72) "Supportive personnel" means unlicensed individuals who:
435	(a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
436	pharmacy technician in nonjudgmental duties not included in the definition of the practice of
437	pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
438	those duties may be further defined by division rule adopted in collaboration with the board;
439	and
440	(b) are supervised by a pharmacist in accordance with rules adopted by the division in
441	collaboration with the board.
442	(73) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501
443	and 58-17b-501.
444	(74) "Unprofessional conduct" means the same as that term is defined in Sections
445	58-1-501 and 58-17b-502 and may be further defined by rule.
446	(75) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
447	dispenses drugs intended for use by animals or for sale to veterinarians for the administration
448	for animals.
449	(76) "Written communication" means a physical document, or an electronic
450	communication, by or from which the recipient may read or access the information intended to
451	be communicated, including:
452	(a) email;
453	(b) text message; and
454	(c) quick response (QR) code.
455	Section 2. Section 58-17b-306 is amended to read:
456	58-17b-306. Qualifications for licensure as a pharmacy.
457	(1) Each applicant for licensure under this section, except for those applying for a class
458	D license, shall:
459	(a) submit a written application in the form prescribed by the division;

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460 (b) pay a fee as determined by the department under Section 63J-1-504; 461 (c) satisfy the division that the applicant, and each owner, officer, or manager of the 462 applicant have not engaged in any act, practice, or omission, which when considered with the 463 duties and responsibilities of a licensee under this section indicates there is cause to believe 464 that issuing a license to the applicant is inconsistent with the interest of the public's health, 465 safety, or welfare; 466 (d) demonstrate the licensee's operations will be in accordance with all federal, state, 467 and local laws relating to the type of activity engaged in by the licensee, including regulations 468 of the Federal Drug Enforcement Administration and Food and Drug Administration; 469 (e) maintain operating standards established by division rule made in collaboration 470 with the board and in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking 471 Act; 472 (f) for each pharmacy [manager, submit] license, ensure that the pharmacist in charge, as defined by the division, submits fingerprint cards and [consent] consents to a fingerprint 473 474 background check in accordance with Section 58-17b-307; and 475 (g) acknowledge the division's authority to inspect the licensee's business premises 476 pursuant to Section 58-17b-103. 477 (2) Each applicant applying for a class D license shall: 478 (a) submit a written application in the form prescribed by the division; 479 (b) pay a fee as determined by the department under Section 63J-1-504; 480 (c) present to the division verification of licensure in the state where physically located 481 and verification that such license is in good standing; 482 (d) satisfy the division that the applicant and each of the applicant's pharmacy 483 managers has not engaged in any act, practice, or omission, which when considered with the 484 duties and responsibilities of a licensee under this section, indicates there is cause to believe 485 that issuing a license to the applicant is inconsistent with the interest of the public's health, 486 safety, or welfare; 487 (e) for each pharmacy manager, submit fingerprint cards and consent to a fingerprint 488 background check in accordance with Section 58-17b-307; (f) provide a statement of the scope of pharmacy services that will be provided and a 489 490 detailed description of the protocol as described by rule by which pharmacy care will be

491	provided, including any collaborative practice arrangements with other health care
492	practitioners;
493	(g) sign an affidavit attesting that any healthcare practitioners employed by the
494	applicant and physically located in Utah have the appropriate license issued by the division and
495	in good standing;
496	(h) sign an affidavit attesting that the applicant will abide by the pharmacy laws and
497	regulations of the jurisdiction in which the pharmacy is located; and
498	(i) if an applicant engages in compounding, submit the most recent inspection report:
499	(i) conducted within two years before the application for licensure; and
500	(ii) (A) conducted as part of the National Association of Boards of Pharmacy Verified
501	Pharmacy Program; or
502	(B) performed by the state licensing agency of the state in which the applicant is a
503	resident and in accordance with the National Association of Boards of Pharmacy multistate
504	inspection blueprint program.
505	(3) (a) Each license issued under this section shall be [issued for] associated with a
506	single, specific address[, and is not transferable or assignable].
507	(b) By rule made in collaboration with the board and in accordance with Title 63G,
508	Chapter 3, Utah Administrative Rulemaking Act, the division shall allow a licensee to update,
509	by request to the division, the address associated with the licensee under Subsection (3)(a), to a
510	new address if the licensee requests the change of address at least 90 days before the day on
511	which the licensee begins operating at the new address.
512	Section 3. Section 58-17b-603 is amended to read:
513	58-17b-603. Identification of pharmacy personnel.
514	[(1)] All individuals employed in a pharmacy facility having any contact with the
515	public or patients receiving services from that pharmacy facility shall wear on their person a
516	clearly visible and readable identification showing the individual's name and position.
517	[(2) When communicating by any means, written, verbal, or electronic, pharmacy
518	personnel must identify themselves as to licensure classification.]
519	Section 4. Section 58-17b-610.6 is amended to read:
520	58-17b-610.6. Hospital pharmacy dispensing prescription drugs.
521	(1) As used in this section, "controlled substance" means a substance classified as a

522	controlled substance under the Controlled Substances Act, Title II, Pub. L. No. 91-513 et seq.,
523	<u>or Section 58-37-4.</u>
524	[(1)] (2) (a) [The] Subject to Subsection (2)(b), the division shall make rules, in
525	accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, in consultation
526	with hospital pharmacies, to establish guidelines under which a hospital pharmacy may
527	dispense a limited supply of a prescription drug to an individual who is no longer a patient in
528	the hospital setting if:
529	$\left[\frac{(a)}{(a)}\right]$ (i) the individual is discharged from the hospital on the same day that the hospital
530	pharmacy dispenses the prescription drug to the individual;
531	(ii) in the professional judgment of the practitioner, dispensing the drug is necessary
532	for the patient's immediate needs;
533	[(b)] (iii) the class A pharmacy with which the patient has an established
534	pharmacy-patient relationship:
535	[(i)] (A) is not open at the time of the patient's discharge; or
536	[(ii)] (B) unable to dispense the medication for any reason;
537	[(c)] (iv) the hospital pharmacy dispenses a quantity of the prescription drug that is not
538	more than a 72-hour supply; and
539	[(d)] (v) dispensing the prescription drug complies with protocols established by the
540	hospital pharmacy.
541	(b) (i) A hospital pharmacy may dispense an opioid antagonist to a patient without
542	satisfying Subsection (2)(a)(iii).
543	(ii) A hospital pharmacy that dispenses an opioid antagonist to a patient under
544	Subsection (2)(b)(i) shall accept as payment the wholesale acquisition cost at the time of
545	dispensing.
546	[(2)] (3) A hospital pharmacy, or a practitioner or pharmacist in the hospital, may
547	dispense a prescription drug in accordance with rules made under Subsection [(1)] (2).
548	Section 5. Section 58-17b-613 is amended to read:
549	58-17b-613. Patient counseling.
550	(1) A pharmacy shall verbally offer to counsel a patient or a patient's agent in a
551	personal face-to-face discussion regarding each prescription drug dispensed, if the patient or
550	nationals a contr

552 patient's agent:

553	(a) delivers the prescription in person to the pharmacist or pharmacy intern; or
554	(b) receives the drug in person at the time it is dispensed at the pharmacy facility.
555	(2) A pharmacist or pharmacy intern at a pharmacy that receives a prescription from a
556	patient by means other than personal delivery, and that dispenses [prescription drugs] a
557	prescribed drug to the patient by means other than personal delivery, shall provide the patient
558	with:
559	[(a) provide patient counseling to a patient regarding each prescription drug the
560	pharmacy dispenses; and]
561	(a) for a class D pharmacy, a toll-free telephone number at which the patient may
562	contact a pharmacist or pharmacy intern at the pharmacy for patient counseling regarding the
563	prescribed drug; or
564	(b) [provide each patient with a toll-free telephone number by which the patient can]
565	for a class A pharmacy, a telephone number by which the patient may contact a pharmacist or
566	pharmacy intern at the pharmacy for [counseling] patient counseling regarding the prescribed
567	<u>drug</u> .
568	(3) Notwithstanding the provisions of Subsections (1) and (2), a pharmacist or a
569	pharmacy intern may:
570	(a) provide patient counseling to an individual under the jurisdiction of the Utah
571	Department of Corrections or a county detention facility via a written, telephone, or electronic
572	communication[-]; and
573	(b) provide medication guides or package inserts via written communication.
574	Section 6. Section 58-17b-614 is amended to read:
575	58-17b-614. Notification.
576	(1) A pharmacy shall report in writing to the division not later than 10 business days:
577	(a) before the date of:
578	(i) a permanent closure of the pharmacy facility;
579	(ii) a change of <u>business</u> name or ownership of the pharmacy facility;
580	(iii) a change of location of the pharmacy facility;
581	(iv) a sale or transfer of any controlled substance as a result of the permanent closing or
582	change of ownership of the pharmacy facility; or
583	(v) any matter or occurrence that the division requires by rule to be reported; or

584	(b) after the day on which:
585	(i) a final administrative disciplinary order is issued against the pharmacy license
586	holder by the regulatory or licensing agency of the state in which the pharmacy is located if the
587	pharmacy is a class D pharmacy;
588	(ii) a final order against a pharmacist is issued who is designated as the
589	pharmacist-in-charge of the pharmacy by the regulatory or licensing agency of the state in
590	which the pharmacy is located if the pharmacy is a class D pharmacy; or
591	(iii) any matter or occurrence that the division requires by rule to be reported.
592	(2) The division may grant a licensee's request to change the business name registered
593	to a licensed pharmacy facility, if there has been no change in the underlying ownership or
594	control of the pharmacy since the last time the business name of the pharmacy was registered
595	or changed.
596	[(2)] (3) A pharmacy shall report in writing to the division a disaster, accident, or
597	emergency that may affect the purity or labeling of a drug, medication, device, or other material
598	used in the diagnosis or treatment of injury, illness, or disease immediately upon the occurrence
599	of the disaster, accident, or emergency as defined by rule.
600	[(3)] (4) A reporting pharmacy shall maintain a copy of any notification required by
601	this section for two years and make a copy available for inspection.
602	The following section is affected by a coordination clause at the end of this bill.
603	Section 7. Section 58-17b-622 is amended to read:
604	58-17b-622. Pharmacy benefit management services Auditing of pharmacy
605	records Appeals.
606	(1) For purposes of this section:
607	(a) "Audit" means a review of the records of a pharmacy by or on behalf of an entity
608	that finances or reimburses the cost of health care services or pharmaceutical products.
609	(b) "Audit completion date" means:
610	(i) for an audit that does not require an on-site visit at the pharmacy, the date on which
611	the pharmacy, in response to the initial audit request, submits records or other documents to the
612	entity conducting the audit, as determined by:
613	(A) postmark or other evidence of the date of mailing; or
614	(B) the date of transmission if the records or other documents are transmitted

615	electronically; and
616	(ii) for an audit that requires an on-site visit at a pharmacy, the date on which the
617	auditing entity completes the on-site visit, including any follow-up visits or analysis which
618	shall be completed within 60 days after the day on which the on-site visit begins.
619	(c) "Entity" includes:
620	(i) a pharmacy benefits manager or coordinator;
621	(ii) a health benefit plan;
622	(iii) a third party administrator as defined in Section 31A-1-301;
623	(iv) a state agency; or
624	(v) a company, group, or agent that represents, or is engaged by, one of the entities
625	described in Subsections (1)(c)(i) through (iv).
626	(d) "Extrapolation" means a method of using a mathematical formula that uses the
627	audit results from a small sample of insurance claims and projects the results over a larger
628	group of insurance claims.
629	[(d)] (e) "Fraud" means an intentional act of deception, misrepresentation, or
630	concealment in order to gain something of value.
631	[(e)] (f) "Health benefit plan" means:
632	(i) a health benefit plan as defined in Section 31A-1-301; or
633	(ii) a health, dental, medical, Medicare supplement, or conversion program offered
634	under Title 49, Chapter 20, Public Employees' Benefit and Insurance Program Act.
635	(2) (a) Except as provided in Subsection (2)(b), this section applies to:
636	(i) a contract for the audit of a pharmacy entered into, amended, or renewed on or after
637	July 1, 2012; and
638	(ii) an entity that conducts an audit of the pharmacy records of a pharmacy licensed
639	under this chapter.
640	(b) This section does not apply to an audit of pharmacy records:
641	(i) for a federally funded prescription drug program, including:
642	(A) the state Medicaid program;
643	(B) the Medicare Part D program;
644	(C) a Department of Defense prescription drug program; and
645	(D) a Veterans Affairs prescription drug program; or

646	(ii) when fraud or other intentional and willful misrepresentation is alleged and the
647	pharmacy audit entity has evidence that the pharmacy's actions reasonably indicate fraud or
648	intentional and willful misrepresentation.
649	(3) (a) An audit that involves clinical or professional judgment shall be conducted by
650	or in consultation with a pharmacist who is employed by or working with the auditing entity
651	and who is licensed in the state or another state.
652	(b) If an audit is conducted on site at a pharmacy, the entity conducting the audit:
653	(i) shall give the pharmacy 10 days advanced written notice of:
654	(A) the audit; and
655	(B) the range of prescription numbers or a date range included in the audit; and
656	(ii) may not audit a pharmacy during the first five business days of the month, unless
657	the pharmacy agrees to the timing of the audit.
658	(c) An entity may not audit claims:
659	(i) submitted more than 18 months prior to the audit, unless:
660	(A) required by federal law; or
661	(B) the originating prescription is dated in the preceding six months; or
662	(ii) that exceed 200 selected prescription claims <u>annually</u> .
663	(d) Subsection (3)(c)(ii) does not apply to any investigative audit that involves fraud,
664	waste, abuse, or willful misrepresentation.
665	(4) (a) An entity may not:
666	(i) include dispensing fees in the calculations of overpayments unless the prescription
667	is considered a misfill;
668	(ii) recoup funds for prescription clerical or recordkeeping errors, including
669	typographical errors, scrivener's errors, and computer errors on a required document or record
670	unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the
671	audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional
672	and willful misrepresentation;
673	(iii) recoup funds for refills dispensed in accordance with Section 58-17b-608.1, unless
674	the health benefit plan does not cover the prescription drug dispensed by the pharmacy;
675	(iv) collect any funds, charge-backs, or penalties until the audit and all appeals are
676	final, unless the audit entity is alleging fraud or other intentional or willful misrepresentation

677	and the audit entity has evidence that the pharmacy's actions reasonably indicate fraud or
678	intentional and willful misrepresentation; or
679	(v) recoup funds or collect any funds, charge-backs, or penalties from a pharmacy in
680	response to a request for audit unless the pharmacy confirms to the entity the date on which the
681	pharmacy received the request for audit.
682	(b) Auditors shall only have access to previous audit reports on a particular pharmacy
683	if the previous audit was conducted by the same entity except as required for compliance with
684	state or federal law.
685	(5) A pharmacy subject to an audit:
686	(a) may use one or more of the following to validate a claim for a prescription, refill, or
687	change in a prescription:
688	(i) electronic or physical copies of records of a health care facility, or a health care
689	provider with prescribing authority;
690	(ii) any prescription that complies with state law;
691	(iii) the pharmacy's own physical or electronic records; or
692	(iv) the physical or electronic records, or valid copies of the physical or electronic
693	records, of a practitioner or health care facility as defined in Section 26B-2-201; and
694	(b) may not be required to provide the following records to validate a claim for a
695	prescription, refill, or change in a prescription:
696	(i) if the prescription was handwritten, the physical handwritten version of the
697	prescription; or
698	(ii) a note from the practitioner regarding the patient or the prescription that is not
699	otherwise required for a prescription under state or federal law.
700	(6) (a) (i) An entity that audits a pharmacy shall establish:
701	(A) a maximum time for the pharmacy to submit records or other documents to the
702	entity following receipt of an audit request for records or documents; and
703	(B) a maximum time for the entity to provide the pharmacy with a preliminary audit
704	report following submission of records under Subsection (6)(a)(i)(A).
705	(ii) The time limits established under Subsections (6)(a)(i)(A) and (B):
706	(A) shall be identical; and
707	(B) may not be less than seven days or more than 60 days.

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708	(iii) An entity that audits a pharmacy may not, after the audit completion date, request
709	additional records or other documents from the pharmacy to complete the preliminary audit
710	report described in Subsection (6)(b).
711	(b) An entity that audits a pharmacy shall provide the pharmacy with a preliminary
712	audit report[,]:
713	(i) delivered to the pharmacy or its corporate office of record, within the time limit
714	established under Subsection (6)(a)(i)(B)[-]; and
715	(ii) that includes a notation and detailed explanation for each suspected error.
716	(c) (i) Except as provided in Subsection (6)(c)(ii), a pharmacy has 30 days following
717	receipt of the preliminary audit report to respond to questions, provide additional
718	documentation, and comment on and clarify findings of the audit.
719	(ii) An entity may grant a reasonable extension under Subsection (6)(c)(i) upon request
720	by the pharmacy.
721	(iii) Receipt of the report under Subsection (6)(c)(i) shall be determined by:
722	(A) postmark or other evidence of the date of mailing; or
723	(B) the date of transmission if the report is transmitted electronically.
724	(iv) If a dispute exists between the records of the auditing entity and the pharmacy, the
725	records maintained by the pharmacy shall be presumed valid for the purpose of the audit.
726	(7) If an audit results in the dispute or denial of a claim, the entity conducting the audit
727	shall allow any of the following:
728	(a) the pharmacy to resubmit a claim using any commercially reasonable method,
729	including fax, mail, or electronic claims submission [provided that the period of time when a
730	claim may be resubmitted has not expired under the rules of the plan sponsor; and] within 30
731	days from the day on which the audit report is received by the pharmacy; or
732	(b) the health benefit plan or other entity that finances or reimburses the cost of health
733	care services or pharmaceutical products to rerun the claim if the health benefit plan or other
734	entity chooses to rerun the claim at no cost to the pharmacy.
735	(8) (a) Within 60 days after the completion of the appeals process under Subsection
736	(9), a final audit report shall be delivered to the pharmacy or its corporate office of record.
737	(b) The final audit report shall include:
738	(i) a disclosure of any money recovered by the entity that conducted the audit[-]; and

739	(ii) legal or contractual information supporting any money recovered, recoupments, or
740	penalties included in the report.
741	(9) (a) An entity that audits a pharmacy shall establish a written appeals process for
742	appealing a preliminary audit report and a final audit report, and shall provide the pharmacy
743	with notice of the written appeals process.
744	(b) If the pharmacy benefit manager's contract or provider manual contains the
745	information required by this Subsection (9), the requirement for notice is met.
746	(10) An auditing entity conducting a pharmacy audit may not:
747	(a) use extrapolation when conducting an audit, including calculating recoupments or
748	penalties for audits, unless otherwise required by federal law or a self-funded insurance plan; or
749	(b) compensate an employee or contractor participating in the audit in a manner that is
750	based on the amount claimed or the actual amount recouped from the pharmacy being audited.
751	Section 8. Section 58-88-202 is amended to read:
752	58-88-202. Dispensing practice Drugs that may be dispensed Limitations and
753	exceptions.
754	(1) Notwithstanding Section 58-17b-302, a dispensing practitioner may dispense a drug
755	at a licensed dispensing practice if the drug is:
756	(a) packaged in a fixed quantity per package by:
757	(i) the drug manufacturer;
758	(ii) a pharmaceutical wholesaler or distributor; or
759	(iii) a pharmacy licensed under Chapter 17b, Pharmacy Practice Act;
760	(b) dispensed:
761	(i) at a licensed dispensing practice at which the dispensing practitioner regularly
762	practices; and
763	(ii) under a prescription issued by the dispensing practitioner to the dispensing
764	practitioner's patient;
765	(c) for a condition that is not expected to last longer than 30 days; and
	() · · · · · · · · · · · · · · · · · · ·
766	(d) for a condition for which the patient has been evaluated by the dispensing
766 767	
	(d) for a condition for which the patient has been evaluated by the dispensing

770	(b) a drug or class of drugs that is designated by the division under Subsection
771	58-88-205(2);
772	(c) gabapentin; or
773	(d) a supply of a drug under this part that exceeds a 30-day supply.
774	(3) A dispensing practitioner may not make a claim against workers' compensation or
775	automobile insurance for a drug dispensed under this part for outpatient use unless the
776	dispensing practitioner is contracted with a pharmacy network established by the claim payor.
777	(4) When a dispensing practitioner dispenses a drug to the patient under this part, a
778	dispensing practitioner shall:
779	(a) disclose to the patient verbally and in writing that the patient is not required to fill
780	the prescription through the licensed dispensing practice and that the patient has a right to fill
781	the prescription through a pharmacy; and
782	(b) if the patient will be responsible to pay cash for the drug, disclose:
783	(i) that the patient will be responsible to pay cash for the drug; and
784	(ii) the amount that the patient will be charged by the licensed dispensing practice for
785	the drug.
786	(5) This part does not:
787	(a) require a dispensing practitioner to dispense a drug under this part;
788	(b) limit a health care prescriber from dispensing under Chapter 17b, Part 8,
789	Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy; or
790	(c) apply to a physician who dispenses:
791	(i) a drug sample, as defined in Section 58-17b-102, to a patient in accordance with
792	Section 58-1-501.3 or Section 58-17b-610; or
793	[(ii) a prescription drug or device to a patient for a patient's immediate need in an
794	emergency department in accordance with Section 58-17b-610.5; or]
795	[(iii)] (ii) a drug in an emergency situation as defined by the division in rule under
796	Chapter 17b, Pharmacy Practice Act.
797	Section 9. Repealer.
798	This bill repeals:
799	Section 58-17b-610.5, Dispensing in emergency department Patient's immediate
800	need.

- 801 Section 10. Effective date.
- 802 This bill takes effect on May 1, 2024.
- 803 Section 11. Coordinating S.B. 207 with H.B. 425.
- 804 If S.B. 207, Pharmacy Practice Act Amendments, and H.B. 425, Health Insurance
- 805 Benefit Amendments, both pass and become law, the Legislature intends that, on January 1,
- 806 2025, the amendments to Section 58-17b-622 in S.B. 207 supersede the amendments to Section
- 807 <u>58-17b-622 in H.B. 425.</u>