DISPENSING MEDICAL PRACTITIONER AMENDMENTS
2013 GENERAL SESSION
STATE OF UTAH
Chief Sponsor: Evan J. Vickers
House Sponsor:
LONG TITLE
General Description:
This bill modifies provisions of the Pharmacy Practice Act to allow certain medical
practitioners to dispense prescription drugs.
Highlighted Provisions:
This bill:
defines terms;
 establishes the license classification "dispensing medical practitioner" under the
Pharmacy Practice Act that permits the following to dispense prescription drugs:
 licensed physicians and surgeons;
 licensed osteopathic physicians and surgeons;
 licensed physician assistants; and
 licensed nurse practitioners;
 establishes that practice as a dispensing medical practitioner does not include the
prescription of a controlled substance; and
 makes technical changes.
Money Appropriated in this Bill:
None
Other Special Clauses:
None
Utah Code Sections Affected:



AMENDS:
58-17b-102, as last amended by Laws of Utah 2012, Chapters 265 and 320
58-17b-612 , as last amended by Laws of Utah 2010, Chapter 101
ENACTS:
58-17b-303.5 , Utah Code Annotated 1953
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

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- 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.
 - (7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created 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 request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.
 - (10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a retail pharmacy to compound or dispense a drug or dispense a device to the public under a prescription order.
 - (11) "Class B pharmacy":
 - (a) means a pharmacy located in Utah:
 - (i) that is authorized to provide pharmaceutical care for patients in an institutional setting; and
 - (ii) whose primary purpose is to provide a physical environment for patients to obtain health care services; and
 - (b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and
 - (ii) pharmaceutical administration and sterile product preparation facilities.
 - (12) "Class C pharmacy" means a pharmacy located in Utah that is authorized to engage in the manufacture, production, wholesale, or distribution of drugs or devices.
 - (13) "Class D pharmacy" means a nonresident pharmacy.
 - (14) "Class E pharmacy" means all other pharmacies.

(15) "Closed-door pharmacy" means a pharmacy that provides pharmaceutical care to a
defined and exclusive group of patients who have 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, but not including a hospital pharmacy, a
retailer of goods to the general public, or the office of a practitioner.

- (16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.
- (17) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients and prevention of disease of human subjects.
- (18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:
- (i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;
- (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or
- (iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
 - (b) "Compounding" does not include:
- (i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;
- (ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner; or
- (iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons.
 - (19) "Confidential information" has the same meaning as "protected health

121	information" under the Standards for Privacy of Individually Identifiable Health Information,
122	45 C.F.R. Parts 160 and 164.
123	(20) "Controlled substance" has the same definition as in Section 58-37-2.
124	(21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
125	417, Sec. 3a(ff) which is incorporated by reference.
126	(22) "Dispense" means the interpretation, evaluation, and implementation of a
127	prescription drug order or device or nonprescription drug or device under a lawful order of a
128	practitioner in a suitable container appropriately labeled for subsequent administration to or use
129	by a patient, research subject, or an animal.
130	(23) "Dispensing medical practitioner" means an individual who is:
131	(a) currently licensed as:
132	(i) a physician and surgeon under Title 58, Chapter 67, Utah Medical Practice Act;
133	(ii) an osteopathic physician and surgeon under Title 58, Chapter 68, Utah Osteopathic
134	Medical Practice Act:
135	(iii) a physician assistant under Title 58, Chapter 70, Physician Assistant Act; or
136	(iv) a nurse practitioner under Title 58, Chapter 31b, Nurse Practice Act; and
137	(b) licensed by this state to engage in practice as a dispensing medical practitioner.
138	[(23)] (24) "Distribute" means to deliver a drug or device other than by administering
139	or dispensing.
140	[(24)] <u>(25)</u> (a) "Drug" means:
141	(i) a substance recognized in the official United States Pharmacopoeia, Official
142	Homeopathic Pharmacopoeia of the United States, or Official National Formulary, or any
143	supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or
144	prevention of disease in humans or animals;
145	(ii) a substance that is required by any applicable federal or state law or rule to be
146	dispensed by prescription only or is restricted to administration by practitioners only;
147	(iii) a substance other than food intended to affect the structure or any function of the
148	body of humans or other animals; and
149	(iv) substances intended for use as a component of any substance specified in
150	Subsections $[(24)]$ (25) (a)(i), (ii), (iii), and (iv).
151	(b) "Drug" does not include dietary supplements.

152	$[\frac{(25)}{(26)}]$ "Drug product equivalent" means a drug product that is designated as the
153	therapeutic equivalent of another drug product in the Approved Drug Products with
154	Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research
155	of the Federal Food and Drug Administration.
156	$\left[\frac{(26)}{(27)}\right]$ "Drug regimen review" includes the following activities:
157	(a) evaluation of the prescription drug order and patient record for:
158	(i) known allergies;
159	(ii) rational therapy-contraindications;
160	(iii) reasonable dose and route of administration; and
161	(iv) reasonable directions for use;
162	(b) evaluation of the prescription drug order and patient record for duplication of
163	therapy;
164	(c) evaluation of the prescription drug order and patient record for the following
165	interactions:
166	(i) drug-drug;
167	(ii) drug-food;
168	(iii) drug-disease; and
169	(iv) adverse drug reactions; and
170	(d) evaluation of the prescription drug order and patient record for proper utilization,
171	including over- or under-utilization, and optimum therapeutic outcomes.
172	[(27)] (28) "Drug sample" means a prescription drug packaged in small quantities
173	consistent with limited dosage therapy of the particular drug, which is marked "sample", is not
174	intended to be sold, and is intended to be provided to practitioners for the immediate needs of
175	patients for trial purposes or to provide the drug to the patient until a prescription can be filled
176	by the patient.
177	[(28)] (29) "Electronic signature" means a trusted, verifiable, and secure electronic
178	sound, symbol, or process attached to or logically associated with a record and executed or
179	adopted by a person with the intent to sign the record.
180	[(29)] (30) "Electronic transmission" means transmission of information in electronic
181	form or the transmission of the exact visual image of a document by way of electronic
182	equipment.

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183	[(30)] (31) "Extern" means a college of pharmacy student enrolled in a college
184	coordinated practical experience program in a health care setting under the supervision of a
185	preceptor, as defined in this act, and approved by a college of pharmacy.
186	[(31)] (32) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to
187	inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
188	under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.
189	[(32)] (33) "Legend drug" has the same meaning as prescription drug.
190	[(33)] (34) "Licensed pharmacy technician" means an individual licensed with the
191	division, that may, under the supervision of a pharmacist, perform the activities involved in the
192	technician practice of pharmacy.
193	[(34)] (35) "Manufacturer" means a person or business physically located in Utah
194	licensed to be engaged in the manufacturing of drugs or devices.
195	[(35)] (<u>36)</u> (a) "Manufacturing" means:
196	(i) the production, preparation, propagation, conversion, or processing of a drug or
197	device, either directly or indirectly, by extraction from substances of natural origin or
198	independently by means of chemical or biological synthesis, or by a combination of extraction
199	and chemical synthesis, and includes any packaging or repackaging of the substance or labeling
200	or relabeling of its container; and
201	(ii) the promotion and marketing of such drugs or devices.
202	(b) "Manufacturing" includes the preparation and promotion of commercially available
203	products from bulk compounds for resale by pharmacies, practitioners, or other persons.
204	(c) "Manufacturing" does not include the preparation or compounding of a drug by a
205	pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation,
206	compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical
207	analysis.
208	[(36)] (37) "Medical order" means a lawful order of a practitioner which may include a
209	prescription drug order.
210	[(37)] (38) "Medication profile" or "profile" means a record system maintained as to
211	drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to

[(38)] (39) "Misbranded drug or device" means a drug or device considered

analyze the profile to provide pharmaceutical care.

214	misbranded under 21 U.S.C.S. Sec. 352 (2003).
215	[(39)] (40) (a) "Nonprescription drug" means a drug which:
216	(i) may be sold without a prescription; and
217	(ii) is labeled for use by the consumer in accordance with federal law.
218	(b) "Nonprescription drug" includes homeopathic remedies.
219	[(40)] (41) "Nonresident pharmacy" means a pharmacy located outside of Utah that
220	sells to a person in Utah.
221	[(41)] (42) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical
222	service.
223	[(42)] (43) "Out-of-state mail service pharmacy" means a pharmaceutical facility
224	located outside the state that is licensed and in good standing in another state, that:
225	(a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in
226	this state pursuant to a lawfully issued prescription;
227	(b) provides information to a patient in this state on drugs or devices which may
228	include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses;
229	or
230	(c) counsels pharmacy patients residing in this state concerning adverse and therapeutic
231	effects of drugs.
232	[(43)] (44) "Patient counseling" means the written and oral communication by the
233	pharmacist or pharmacy intern of information, to the patient or caregiver, in order to ensure
234	proper use of drugs, devices, and dietary supplements.
235	[44)] (45) "Pharmaceutical administration facility" means a facility, agency, or
236	institution in which:
237	(a) prescription drugs or devices are held, stored, or are otherwise under the control of
238	the facility or agency for administration to patients of that facility or agency;
239	(b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist
240	or pharmacy intern with whom the facility has established a prescription drug supervising
241	relationship under which the pharmacist or pharmacy intern provides counseling to the facility
242	or agency staff as required, and oversees drug control, accounting, and destruction; and
243	(c) prescription drugs are professionally administered in accordance with the order of a
244	practitioner by an employee or agent of the facility or agency.

245	[(45)] (46) (a) "Pharmaceutical care" means carrying out the following in collaboration
246	with a prescribing practitioner, and in accordance with division rule:
247	(i) designing, implementing, and monitoring a therapeutic drug plan intended to
248	achieve favorable outcomes related to a specific patient for the purpose of curing or preventing
249	the patient's disease;
250	(ii) eliminating or reducing a patient's symptoms; or
251	(iii) arresting or slowing a disease process.
252	(b) "Pharmaceutical care" does not include prescribing of drugs without consent of a
253	prescribing practitioner.
254	[(46)] (47) "Pharmaceutical facility" means a business engaged in the dispensing,
255	delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within
256	or into this state.
257	[(47)] (48) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical
258	facility engaged in the business of wholesale vending or selling of any prescription drug or
259	device to other than the consumer or user of the prescription drug or device, which the
260	pharmaceutical facility has not produced, manufactured, compounded, or dispensed.
261	(b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical
262	facility carrying out the following business activities:
263	(i) intracompany sales;
264	(ii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,
265	purchase or trade a prescription drug or device between hospitals or other health care facilities
266	that are under common ownership or control of the management and operation of the facilities;
267	(iii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,
268	purchase, or trade a prescription drug or device for emergency medical reasons, or to supply
269	another pharmaceutical facility to alleviate a temporary shortage; or
270	(iv) the distribution of a prescription drug or device as a sample by representatives of a
271	manufacturer.
272	[(48)] (49) "Pharmacist" means an individual licensed by this state to engage in the
273	practice of pharmacy.
274	[(49)] (50) "Pharmacist-in-charge" means a pharmacist currently licensed in good

standing who accepts responsibility for the operation of a pharmacy in conformance with all

276 laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is 277 personally in full and actual charge of the pharmacy and all personnel. 278 [(50)] (51) "Pharmacist preceptor" means a licensed pharmacist in good standing with 279 one or more years of licensed experience. The preceptor serves as a teacher, example of 280 professional conduct, and supervisor of interns in the professional practice of pharmacy. 281 [(51)] (52) "Pharmacy" means any place where: 282 (a) drugs are dispensed; (b) pharmaceutical care is provided: 283 284 (c) drugs are processed or handled for eventual use by a patient; or 285 (d) drugs are used for the purpose of analysis or research. 286 [(52)] (53) "Pharmacy benefits manager or coordinator" means a person or entity that 287 provides pharmacy benefit management services as defined in Section 49-20-502 on behalf of a 288 self-insured employer, insurance company, health maintenance organization, or other plan 289 sponsor, as defined by rule. 290 [(53)] (54) "Pharmacy intern" means an individual licensed by this state to engage in 291 practice as a pharmacy intern. 292 [(54)] (55) "Pharmacy technician training program" means an approved technician 293 training program providing education for pharmacy technicians. 294 (56) (a) "Practice as a licensed dispensing medical practitioner" means the practice of 295 pharmacy, specifically relating to the dispensing of a prescription drug in accordance with the 296 scope of practice defined in division rule in collaboration with the board. 297 (b) "Practice as a licensed dispensing medical practitioner" does not include dispensing 298 a controlled substance as defined in Section 58-37-2. 299 [(55)] (57) (a) "Practice as a licensed pharmacy technician" means engaging in practice 300 as a pharmacy technician under the general supervision of a licensed pharmacist and in 301 accordance with a scope of practice defined by division rule made in collaboration with the 302 board. 303 (b) "Practice as a licensed pharmacy technician" does not include: 304 (i) performing a drug utilization review, prescription drug order clarification from a 305 prescriber, final review of the prescription and prescribed drug prepared for dispensing,

dispensing of the drug, or counseling a patient with respect to a prescription drug;

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307	(11) counseling regarding nonprescription drugs and dietary supplements unless
308	delegated by the supervising pharmacist; or
309	(iii) receiving new prescription drug orders when communicating telephonically or
310	electronically unless the original information is recorded so the pharmacist may review the
311	prescription drug order as transmitted.
312	[(56)] (58) "Practice of pharmacy" includes the following:
313	(a) providing pharmaceutical care;
314	(b) collaborative pharmacy practice in accordance with a collaborative pharmacy
315	practice agreement;
316	(c) compounding, packaging, labeling, dispensing, administering, and the coincident
317	distribution of prescription drugs or devices, provided that the administration of a prescription
318	drug or device is:
319	(i) pursuant to a lawful order of a practitioner when one is required by law; and
320	(ii) in accordance with written guidelines or protocols:
321	(A) established by the licensed facility in which the prescription drug or device is to be
322	administered on an inpatient basis; or
323	(B) approved by the division, in collaboration with the board and the Physicians
324	Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be
325	administered on an outpatient basis solely by a licensed pharmacist;
326	(d) participating in drug utilization review;
327	(e) ensuring proper and safe storage of drugs and devices;
328	(f) maintaining records of drugs and devices in accordance with state and federal law
329	and the standards and ethics of the profession;
330	(g) providing information on drugs or devices, which may include advice relating to
331	therapeutic values, potential hazards, and uses;
332	(h) providing drug product equivalents;
333	(i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
334	technicians;
335	(j) providing patient counseling, including adverse and therapeutic effects of drugs;
336	(k) providing emergency refills as defined by rule;
337	(l) telepharmacy; and

338	(m) formulary management intervention.
339	[(57)] (59) "Practice of telepharmacy" means the practice of pharmacy through the use
340	of telecommunications and information technologies.
341	[(58)] (60) "Practice of telepharmacy across state lines" means the practice of
342	pharmacy through the use of telecommunications and information technologies that occurs
343	when the patient is physically located within one jurisdiction and the pharmacist is located in
344	another jurisdiction.
345	[(59)] (61) "Practitioner" means an individual currently licensed, registered, or
346	otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the
347	course of professional practice.
348	[(60)] (62) "Prescribe" means to issue a prescription:
349	(a) orally or in writing; or
350	(b) by telephone, facsimile transmission, computer, or other electronic means of
351	communication as defined by division rule.
352	[(61)] (63) "Prescription" means an order issued:
353	(a) by a licensed practitioner in the course of that practitioner's professional practice of
354	by collaborative pharmacy practice agreement; and
355	(b) for a controlled substance or other prescription drug or device for use by a patient
356	or an animal.
357	[(62)] (64) "Prescription device" means an instrument, apparatus, implement, machine
358	contrivance, implant, in vitro reagent, or other similar or related article, and any component
359	part or accessory, which is required under federal or state law to be prescribed by a practitione
360	and dispensed by or through a person or entity licensed under this chapter or exempt from
361	licensure under this chapter.
362	[(63)] (65) "Prescription drug" means a drug that is required by federal or state law or
363	rule to be dispensed only by prescription or is restricted to administration only by practitioners
364	[(64)] (66) "Retail pharmacy" means a pharmaceutical facility dispensing prescription
365	drugs and devices to the general public.
366	[(65)] (67) "Self-audit" means an internal evaluation of a pharmacy to determine
367	compliance with this chapter.
368	[(66)] (68) "Supervising pharmacist" means a pharmacist who is overseeing the

369	operation of the pharmacy during a given day or shift.
370	[(67)] (69) "Supportive personnel" means unlicensed individuals who:
371	(a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
372	pharmacy technician in nonjudgmental duties not included in the definition of the practice of
373	pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
374	those duties may be further defined by division rule adopted in collaboration with the board;
375	and
376	(b) are supervised by a pharmacist in accordance with rules adopted by the division in
377	collaboration with the board.
378	[(68)] (70) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.
379	[(69)] (71) "Unprofessional conduct" is as defined in Sections 58-1-501 and
380	58-17b-502 and may be further defined by rule.
381	[(70)] (72) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
382	dispenses drugs intended for use by animals or for sale to veterinarians for the administration
383	for animals.
384	Section 2. Section 58-17b-303.5 is enacted to read:
385	58-17b-303.5. Qualifications for licensure as a dispensing medical practitioner.
386	An applicant for licensure as a dispensing medical practitioner shall:
387	(1) submit an application in a form prescribed by the division;
388	(2) pay a fee as determined by the department under Section 63J-1-504;
389	(3) produce satisfactory evidence of good moral character as it relates to the applicant's
390	ability to practice pharmacy;
391	(4) complete a criminal background check and be free from criminal convictions as
392	described in Section 58-1-501;
393	(5) have no physical or mental condition of a nature that prevents the applicant from
394	engaging in the practice of pharmacy with reasonable skill, competency, and safety to the
395	public;
396	(6) meet the preliminary educational qualifications required by division rule and in
397	collaboration with the board; and
398	(7) have successfully passed examinations required by division rule made in
399	collaboration with the board.

400	Section 5. Section 58-170-612 is amended to read:
401	58-17b-612. Supervision Pharmacist-in-charge.
402	(1) (a) Any pharmacy, except a wholesaler, distributor, out-of-state mail service
403	pharmacy, or class E pharmacy, shall be under the general supervision of at least one
404	pharmacist licensed to practice in Utah. One pharmacist licensed in Utah shall be designated
405	as the pharmacist-in-charge, whose responsibility it is to oversee the operation of the pharmacy.
406	(b) Notwithstanding Subsection 58-17b-102[(66)](68), a supervising pharmacist does
407	not have to be in the pharmacy or care facility but shall be available via a telepharmacy system
408	for immediate contact with the supervised pharmacy technician or pharmacy intern if:
409	(i) the pharmacy is located in:
410	(A) a remote rural hospital, as defined in Section 26-21-13.6; or
411	(B) a clinic located in a remote rural county with less than 20 people per square mile;
412	(ii) the supervising pharmacist described in Subsection (1)(a) is not available; and
413	(iii) the telepharmacy system maintains records and files quarterly reports as required
414	by division rule to assure that patient safety is not compromised.
415	(2) Each out-of-state mail service pharmacy shall designate and identify to the division
416	a pharmacist holding a current license in good standing issued by the state in which the
417	pharmacy is located and who serves as the pharmacist-in-charge for all purposes under this
418	chapter.

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