

RULE ANALYSIS

Introduction: THE NEW RULE IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED RULE

Short Title: Class I Pharmacy

Rule Numbers: §291.157

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy;
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act; and
- (3) Section 560.053 authorizes the Board to adopt rules establishing additional pharmacy classifications.

Purpose: The new rule, if adopted, creates a new class of pharmacy (Class I) for pharmacies located in a physician's office. The new rules, if adopted, limit the types of drugs that may be dispensed from the pharmacy and set forth the requirements for the operation of the pharmacy.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER H OTHER CLASSES OF PHARMACY

5
6 **§291.157 Pharmacy Located in Physician's Office (Class I)**
7

8 **(a) Purpose.** The purpose of this section is to create a new class of pharmacy for a
9 **pharmacy located in a physician's office and to provide standards in the conduct,**
10 **practice activities, and operation of a pharmacy located in a physician's office.**

11
12 **(a) Definitions.** The following words and terms, when used in this section, shall have the
13 **following meanings, unless the context clearly indicates otherwise. All other words and**
14 **terms shall have the meanings defined in the Act.**

15
16 **(1) Act--The Texas Pharmacy Act, Chapters 551-569, Occupations Code as amended.**

17
18 **(2) Administer--The direct application of a prescription drug by injection, inhalation,**
19 **ingestion, or any other means to the body of a patient by:**

20
21 **(A) a practitioner or an authorized agent under his supervision; or**

22
23 **(B) the patient at the direction of a practitioner.**

24
25 **(3) Board--The Texas State Board of Pharmacy.**

26
27 **(4) Continuous supervision--Supervision provided by the pharmacist-in-charge and/or**
28 **staff pharmacist(s), and consists of on-site and electronic supervision, routine**
29 **inspection, and a policy and procedure manual.**

30
31 **(5) Dangerous drug--Any drug or device that is not included in Penalty Groups 1-4 of the**
32 **Controlled Substances Act and that is unsafe for self-medication or any drug or device**
33 **that bears or is required to bear the legend:**

34
35 **(A) "Caution: federal law prohibits dispensing without prescription" or "Rx only";**

36
37 **(B) "Caution: federal law restricts this drug to use by or on the order of a licensed**
38 **veterinarian."**

39
40 **(6) Dispense--Preparing, packaging, compounding, or labeling for delivery a**
41 **prescription drug or device in the course of professional practice to an ultimate user or**
42 **his agent by or pursuant to the lawful order of a practitioner.**

43
44 **(7) Pharmacist--A person licensed by the board to practice pharmacy.**

45
46 **(8) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the**
47 **pharmacist who is responsible for a pharmacy's compliance with laws and rules**
48 **pertaining to the practice of pharmacy.**
49

50 (9) Pharmacy technician trainee--An individual who is registered with the board as a
51 pharmacy technician trainee and is authorized to participate in a pharmacy's technician
52 training program.

53
54 (10) Practitioner--

55
56 (A) a person licensed or registered to prescribe, distribute, administer, or dispense a
57 prescription drug or device in the course of professional practice in this state, including
58 a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under the
59 Act;

60
61 (B) a person licensed by another state, Canada, or the United Mexican States in a
62 health field in which, under the law of this state, a license holder in this state may legally
63 prescribe a dangerous drug;

64
65 (C) a person practicing in another state and licensed by another state as a physician,
66 dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement
67 Administration registration number and who may legally prescribe a Schedule II, III, IV, or
68 V controlled substance, as specified under Chapter 481, Health and Safety Code, in that
69 other state; or

70
71 (D) an advanced practice registered nurse or physician assistant to whom a physician
72 has delegated the authority to prescribe or order drugs or devices under Chapter 157 of
73 the Medical Practice Act (Subtitle B, Occupations Code).

74
75 (11) Still image capture--A specific image captured electronically from a video or other
76 image capture device.

77
78 (12) Store and forward--A video or still image record which is saved electronically for
79 future review.

80
81 (b) Personnel.

82
83 (1) Pharmacist-in-charge.

84
85 (A) Each Class I pharmacy shall have one pharmacist-in-charge who is employed or
86 under written agreement, at least on a part-time basis, but may be employed on a full-
87 time basis if desired, and who may be pharmacist-in-charge of no more than three Class I
88 pharmacies.

89
90 (B) A written agreement shall exist between the Class I pharmacy and the pharmacist-in-
91 charge, and a copy of the written agreement shall be made available to the board upon
92 request.

93
94 (C) The pharmacist-in-charge shall have at a minimum, the responsibility for the
95 following:

96
97 (i) continuous supervision of registered nurses, licensed vocational nurses, physician
98 assistants, pharmacy technicians, and pharmacy technician trainees, carrying out the
99 pharmacy related aspects of provision;

100

101 (ii) documenting periodic on-site visits as specified in paragraph (2)(D) of this
102 subsection, either personally or by the staff pharmacist, to ensure that the Class I
103 pharmacy is following set policies and procedures; documentation shall be as specified
104 in subsection (d)(4) of this section;

105
106 (iii) procuring and storing drugs and/or devices, but he or she may receive input from
107 other appropriate staff of the physician's office;

108
109 (iv) determining specifications of all drugs procured by the pharmacy;

110
111 (v) maintaining records of all transactions of the pharmacy as may be required by
112 applicable law and as may be necessary to maintain accurate control over and
113 accountability for all drugs;

114
115 (vi) developing and at least annual review of a policy and procedure manual for the
116 pharmacy;

117
118 (vii) meeting inspection and other requirements of the Texas Pharmacy Act and these
119 sections;

120
121 (viii) dispensing of prescription drug orders; and

122
123 (ix) ensuring all operations at the Class I pharmacy, including supervision, and
124 compliance with this section.

125
126 **(2) Staff pharmacists.**

127
128 (A) The pharmacist-in-charge may be assisted by a sufficient number of additional
129 pharmacists as may be required to operate the pharmacy competently, safely, and
130 adequately to meet the needs of the patients.

131
132 (B) Staff pharmacists shall assist the pharmacist-in-charge in meeting the
133 responsibilities as outlined in paragraph (1) of this subsection, and in ordering,
134 supervising, and accounting for drugs.

135
136 (C) Staff pharmacists shall be responsible for any delegated act performed by pharmacy
137 technicians under his or her supervision.

138
139 (D) A dispensing pharmacist shall be responsible for and ensure that the drug is
140 dispensed and delivered safely, and accurately as prescribed, unless the pharmacy's
141 data processing system can record the identity of each pharmacist involved in a specific
142 portion of the dispensing processing. If the system can track the identity of each
143 pharmacist involved in the dispensing process, each pharmacist involved in the
144 dispensing process shall be responsible for and ensure that the portion of the process
145 the pharmacist is performing results in the safe and accurate dispensing and delivery of
146 the drug as prescribed. The dispensing process shall include, but not be limited to, drug
147 regimen review and verification of accurate prescription data entry, including data entry
148 of prescriptions placed on hold, packaging, preparation, compounding, transferring, and
149 labeling, and performance of the final check of the dispensed prescription. An intern has
150 the same responsibilities described in this subparagraph as a pharmacist but must
151 perform his or her duties under the supervision of a pharmacist.

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(E) Duties which may only be performed by a pharmacist are as follows:

(i) receiving oral prescription drug orders and reducing these orders to writing, either manually or electronically;

(ii) interpreting prescription drug orders;

(iii) selecting drug products;

(iv) performing the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed;

(v) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant;

(vi) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;

(vii) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(viii) interpreting patient medication records and performing drug regimen reviews; and

(ix) personally visiting the Class I pharmacy on at least a monthly basis to ensure that the pharmacy is following established policies and procedures.

(3) Pharmacy Technicians.

(A) All pharmacy technicians shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Pharmacy technicians may not perform any of the duties listed in paragraph (2)(E) of this subsection.

(C) A pharmacist may delegate to pharmacy technicians any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(i) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians; and

(ii) pharmacy technicians are under the continuous supervision of and responsible to a pharmacist.

(D) Pharmacy technicians may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs, as follows:

(i) initiating and receiving refill authorization requests;

- 203
204 (ii) entering prescription data into a data processing system;
205
206 (iii) selecting a stock container from the shelf for a prescription;
207
208 (iv) preparing and packaging prescription drug orders; and
209
210 (v) affixing prescription labels and auxiliary labels to the prescription container.

211
212 (4) Owner. The owner of a Class I pharmacy shall have responsibility for all
213 administrative and operational functions of the pharmacy. The pharmacist-in-charge may
214 advise the owner on administrative and operational concerns. The owner shall have
215 responsibility for, at a minimum, the following, and if the owner is not a Texas licensed
216 pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas
217 licensed pharmacist:

218
219 (A) establishing policies for procurement of prescription drugs dispensed from the
220 pharmacy;

221
222 (B) establishing and maintaining effective controls against the theft or diversion of
223 prescription drugs;

224
225 (C) providing the pharmacy with the necessary equipment and resources
226 commensurate with its level and type of practice; and

227
228 (D) establishing policies and procedures regarding maintenance, storage, and retrieval
229 of records in a data processing system such that the system is in compliance with state
230 and federal requirements.

231
232 (5) Identification of pharmacy personnel. All pharmacy personnel shall be identified as
233 follows.

234
235 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or
236 badge that bears the person's name and identifies him or her as a pharmacy technician,
237 or a certified pharmacy technician, if the technician maintains current certification with
238 the Pharmacy Technician Certification Board or any other entity providing an
239 examination approved by the board.

240
241 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an
242 identification tag or badge that bears the person's name and identifies him or her as a
243 pharmacy technician trainee.

244
245 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge
246 that bears the person's name and identifies him or her as a pharmacist intern.

247
248 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the
249 person's name and identifies him or her as a pharmacist.

250
251 (c) Operational Standards.

252
253 (1) Registration.

- 254
255 (A) All Class I pharmacies shall register with the board on a form provided by the
256 board, following the procedures specified in §291.1 of this title (relating to Pharmacy
257 License Application).
- 258
259 (B) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
260 charged for the issuance of a new license and for each renewal.
- 261
262 (C) A Class I pharmacy which changes ownership shall notify the board within ten
263 days of the change of ownership and apply for a new and separate license as specified in
264 §291.3 of this title (relating to Required Notifications).
- 265
266 (D) A Class I pharmacy which changes location and/or name shall notify the board
267 within ten days of the change and file for an amended license as specified in §291.3 of
268 this title.
- 269
270 (E) A separate license is required for each principal place of business and only one
271 pharmacy license may be issued to a specific location.
- 272
273 (F) A Class I pharmacy shall notify the board in writing within 10 days of permanent
274 closing following the procedures as specified in §291.5 of this title (relating to Closing a
275 Pharmacy).

276
277 **(2) Environment/Security.**

278
279 (A) A Class I pharmacy shall be under the continuous supervision of a pharmacist at all
280 times the site is open to provide pharmacy services. To qualify as continuous
281 supervision, the pharmacist is not required to be physically present at the Class I
282 pharmacy but shall supervise the pharmacy electronically through the use of the
283 following types of technology:

284
285 (i) audio and video;

286
287 (ii) still image capture; and

288
289 (iii) store and forward.

290
291 (B) Drugs for use in the pharmacy shall be stored in an area that is:

292
293 (i) separate from any other drugs used at the physician's office; and

294
295 (ii) locked by key, combination or other mechanical or electronic means, so as to
296 prohibit access by unauthorized personnel.

297
298 (C) A sink with hot and cold running water shall be available to all pharmacy personnel
299 and shall be maintained in a sanitary condition at all times.

300
301 (D) Access to the area where drugs are stored at the pharmacy shall be limited to
302 pharmacists or personnel who:

303
304 (i) are licensed healthcare providers or pharmacy technicians;

305
306 (ii) are designated in writing by the pharmacist-in-charge; and
307
308 (iii) have completed documented training concerning their duties associated with
309 the pharmacy.
310
311 (E) The pharmacy shall have adequate security and procedures to:
312
313 (I) comply with federal and state laws and regulations; and
314
315 (II) maintain patient confidentiality.
316
317 (3) Equipment. Each Class I pharmacy shall maintain the following equipment and
318 supplies:
319
320 (A) a data processing system including a printer or comparable equipment; and
321
322 (B) an adequate supply of prescription, poison, and other applicable identification
323 labels used in dispensing and providing drugs.
324
325 (4) Library. A reference library shall be maintained which includes the following in hard
326 copy or electronic format:
327
328 (A) current copies of the following:
329
330 (i) Texas Pharmacy Act and rules; and
331
332 (ii) Texas Dangerous Drug Act;
333
334 (B) current copies of at least two of the following references:
335
336 (i) Facts and Comparisons with current supplements;
337
338 (ii) Physician's Desk Reference (PDR);
339
340 (iii) American Drug Index;
341
342 (iv) a reference text on drug interactions, such as Drug Interaction Facts. A separate
343 reference is not required if other references maintained by the pharmacy contain drug
344 interaction information including information needed to determine severity or
345 significance of the interaction and appropriate recommendations or actions to be taken;
346
347 (v) reference texts in any of the following subjects: toxicology, pharmacology, or drug
348 interactions; or
349
350 (vi) reference texts pertinent to the major function(s) of the clinic.
351
352 (5) Drugs and devices.
353
354 (A) A Class I pharmacy shall be limited to the following types of drugs exclusive of
355 nonprescription drugs:

- 356
357 (i) Bimatoprost (Latisse);
358 (ii) Hydroquinone (Lustra, Claripel); and
359 (iii) Tretinoin (Retin A).

360
361 (B) All drugs shall be stored at the proper temperatures, as defined in §291.15 of this
362 title (relating to Storage of Drugs).

363
364 (C) Any drug bearing an expiration date may not be provided, dispensed, or
365 administered beyond the expiration date of the drug or device. Outdated drugs shall be
366 removed from stock and shall be quarantined together until such drugs or devices are
367 disposed.

368
369 (D) Controlled substances may not be stored at the pharmacy.

370
371 (E) Class I Pharmacies may not sell, purchase, trade or possess prescription drug
372 samples, unless the pharmacy meets the requirements as specified in §291.16 of this title
373 (relating to Samples).

374
375 (6) Prescription dispensing and delivery.

376
377 (A) Drugs shall only be dispensed at the pharmacy after receipt of an original
378 prescription drug order.

379
380 (B) To optimize drug therapy, a pharmacist shall communicate to the patient or the
381 patient's agent, information about the prescription drug or device which in the exercise
382 of the pharmacist's professional judgment the pharmacist deems significant, such as the
383 following:

384
385 (i) name and description of the drug or device;

386
387 (ii) dosage form, dosage, route of administration, and duration of drug therapy;

388
389 (iii) special directions and precautions for preparation, administration, and use by the
390 patient;

391
392 (iv) common severe side or adverse effects or interactions and therapeutic
393 contraindications that may be encountered, including their avoidance, and the action
394 required if they occur;

395
396 (v) techniques for self-monitoring of drug therapy;

397
398 (vi) proper storage;

399
400 (vii) refill information; and

401
402 (viii) action to be taken in the event of a missed dose.

403
404 (C) Such communication shall be:

405
406 (i) provided with each new prescription drug order;

407
408 (ii) provided for any prescription drug order dispensed by the pharmacy on the
409 request of the patient or patient's agent;
410
411 (iii) communicated orally in person unless the patient or patient's agent is not at the
412 pharmacy or a specific communication barrier prohibits such oral communication;
413
414 (iv) documented by recording the initials or identification code of the pharmacist
415 providing the counseling in the prescription dispensing record as follows:
416
417 (I) on the original hard-copy prescription, provided the counseling pharmacist
418 clearly records his or her initials on the prescription for the purpose of identifying who
419 provided the counseling;
420
421 (II) in the pharmacy's data processing system;
422
423 (III) in an electronic logbook; or
424
425 (IV) in a hard-copy log; and
426
427 (v) reinforced with written information relevant to the prescription and provided to the
428 patient or patient's agent. The following is applicable concerning this written information.
429
430 (I) Written information must be in plain language designed for the patient and
431 printed in an easily readable font size comparable to but no smaller than ten-point Times
432 Roman.
433
434 (II) When a compounded preparation is dispensed, information shall be provided for
435 the major active ingredient(s), if available.
436
437 (III) For new drug entities, if no written information is initially available, the
438 pharmacist is not required to provide information until such information is available,
439 provided:
440
441 (-a) the pharmacist informs the patient or the patient's agent that the product is a
442 new drug entity and written information is not available;
443
444 (-b) the pharmacist documents the fact that no written information was provided;
445 and
446
447 (-c) if the prescription is refilled after written information is available, such
448 information is provided to the patient or patient's agent.
449
450 (IV) The written information accompanying the prescription or the prescription label
451 shall contain the statement "Do not flush unused medications or pour down a sink or
452 drain." A drug product on a list developed by the Federal Food and Drug Administration
453 of medicines recommended for disposal by flushing is not required to bear this
454 statement.
455
456 (D) Only a pharmacist may verbally provide drug information to a patient or patient's
457 agent and answer questions concerning prescription drugs. Non-pharmacist personnel

458 may not ask questions of a patient or patient's agent which are intended to screen and/or
459 limit interaction with the pharmacist.

460
461 (E) Nothing in this subparagraph shall be construed as requiring a pharmacist to
462 provide consultation when a patient or patient's agent refuses such consultation. The
463 pharmacist shall document such refusal for consultation.

464
465 (F) For the purpose of promoting therapeutic appropriateness, a pharmacist shall,
466 prior to or at the time of dispensing a prescription drug order, review the patient's
467 medication record. Such review shall at a minimum identify clinically significant:

468
469 (i) known allergies;

470
471 (ii) rational therapy-contraindications;

472
473 (iii) reasonable dose and route of administration;

474
475 (iv) reasonable directions for use;

476
477 (v) duplication of therapy;

478
479 (vi) drug-drug interactions;

480
481 (vii) drug-food interactions;

482
483 (viii) drug-disease interactions;

484
485 (ix) adverse drug reactions; and

486
487 (x) proper utilization, including overutilization or underutilization.

488
489 (G) Upon identifying any clinically significant conditions, situations, or items listed in
490 subparagraph (F) of this paragraph, the pharmacist shall take appropriate steps to avoid
491 or resolve the problem including consultation with the prescribing practitioner. The
492 pharmacist shall document such occurrences as specified in subparagraph (I) of this
493 paragraph.

494
495 (H) Prior to dispensing, any questions regarding a prescription drug order must be
496 resolved with the prescriber and written documentation of these discussions made and
497 maintained as specified in subparagraph (I) of this paragraph.

498
499 (I) When a pharmacist consults a prescriber as described in subparagraph (G) and (H)
500 of this paragraph the pharmacist shall document on the hard-copy or in the pharmacy's
501 data processing system associated with the prescription such occurrences and shall
502 include the following information:

503
504 (i) date the prescriber was consulted;

505
506 (ii) name of the person communicating the prescriber's instructions;

507
508 (iii) any applicable information pertaining to the consultation; and

509
510 (iv) initials or identification code of the pharmacist performing the consultation
511 clearly recorded for the purpose of identifying the pharmacist who performed the
512 consultation if on the information is recorded on the hard-copy prescription.
513
514 (J) Generic Substitution. A pharmacist may dispense a generically equivalent drug
515 product and shall comply with the provisions of §309.3 of this title (relating to Generic
516 Substitution).
517
518 (K) At the time of delivery of the drug, the dispensing container shall bear a label in
519 plain language and printed in an easily readable font size, unless otherwise specified,
520 with at least the following information:
521
522 (i) name, address and phone number of the pharmacy;
523
524 (ii) unique identification number of the prescription that is printed in an easily
525 readable font size comparable to but no smaller than ten-point Times Roman;
526
527 (iii) date the prescription is dispensed;
528
529 (iv) initials or an identification code of the dispensing pharmacist;
530
531 (v) name of the prescribing practitioner;
532
533 (vi) name of the patient or if such drug was prescribed for an animal, the species of
534 the animal and the name of the owner that is printed in an easily readable font size
535 comparable to but no smaller than ten-point Times Roman. The name of the patient's
536 partner or family member is not required to be on the label of a drug prescribed for a
537 partner for a sexually transmitted disease or for a patient's family members if the patient
538 has an illness determined by the Centers for Disease Control and Prevention, the World
539 Health Organization, or the Governor's office to be pandemic;
540
541 (vii) instructions for use that is printed in an easily readable font size comparable to
542 but no smaller than ten-point Times Roman;
543
544 (viii) quantity dispensed;
545
546 (ix) appropriate ancillary instructions such as storage instructions or cautionary
547 statements such as warnings of potential harmful effects;
548
549 (x) if the pharmacist has selected a generically equivalent drug pursuant to the
550 provisions of the Act, Chapter 562, the statement "Substituted for Brand Prescribed" or
551 "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the brand
552 name product prescribed;
553
554 (xi) the name and strength of the actual drug product dispensed that is printed in an
555 easily readable font size comparable to but no smaller than ten-point Times Roman,
556 unless otherwise directed by the prescribing practitioner;
557
558 (l) The name shall be either:
559

560 _____ (-a) the brand name; or

561
562 _____ (-b) if no brand name, then the generic name and name of the manufacturer or
563 distributor of such generic drug. (The name of the manufacturer or distributor may be
564 reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient
565 to identify the manufacturer or distributor. For combination drug products or non-sterile
566 compounded drug preparations having no brand name, the principal active ingredients
567 shall be indicated on the label.)

568
569 _____ (II) Except as provided in clause (xii) of this subparagraph, the brand name of the
570 prescribed drug shall not appear on the prescription container label unless it is the drug
571 product actually dispensed; and

572
573 _____ (xii) either on the prescription label or the written information accompanying the
574 prescription, the statement "Do not flush unused medications or pour down a sink or
575 drain." A drug product on a list developed by the Federal Food and Drug Administration
576 of medicines recommended for disposal by flushing is not required to bear this
577 statement.

578
579 _____ (L) If the prescription label required in subparagraph (K) of this paragraph is printed in
580 a type size smaller than ten-point Times Roman, the pharmacy shall provide the patient
581 written information containing the information as specified in subparagraph (K) of this
582 paragraph in an easily readable font size comparable to but no smaller than ten-point
583 Times Roman.

584
585 _____ (M) The label is not required to include the initials or identification code of the
586 dispensing pharmacist as specified in subparagraph (A) of this paragraph if the identity
587 of the dispensing pharmacist is recorded in the pharmacy's data processing system. The
588 record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's
589 data processing system.

590
591 _____ (N) A pharmacist shall perform the final check of the dispensed prescription before
592 delivery to the patient to ensure that the prescription has been dispensed accurately as
593 prescribed. If the pharmacist is not present at the Class I pharmacy the final check shall
594 be accomplished through a visual check using electronic methods.

595
596 (7) Policies and procedures.

597
598 _____ (A) A Class I pharmacy shall operate according to written policies and procedures.

599
600 _____ (B) The policy and procedure manual shall include, but not be limited to, the following:

601
602 _____ (i) a current list of the name and contact information of the pharmacist-in-charge and
603 personnel designated by the pharmacist-in-charge to have:

604
605 _____ (I) have access to the pharmacy; and

606
607 _____ (II) operate the pharmacy in the absence of a pharmacist;

608
609 _____ (ii) functions of the pharmacist-in-charge, staff pharmacist(s), and pharmacy
610 technicians;

611
612 (iii) a copy of written agreement between the pharmacist-in-charge and the Class I
613 pharmacy;
614
615 (iv) date of last review/revision of policy and procedure manual; and
616
617 (v) policies and procedures for:
618
619 (I) operation of the Class I pharmacy;
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621 (II) security;
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623 (III) equipment;
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625 (IV) sanitation;
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627 (V) licensing;
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629 (VI) reference materials;
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631 (VII) storage of drugs;
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633 (VIII) dispensing;
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635 (IX) drug regimen review;
636
637 (X) supervision;
638
639 (XI) labeling;
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641 (XII) drug destruction and returns;
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643 (XIII) drug procuring;
644
645 (XIV) receiving of drugs;
646
647 (XV) delivery of drugs;
648
649 (XVI) recordkeeping; and
650
651 (XVII) inspection.
652
653 (vi) The written policies and procedures shall be reviewed and revised if necessary, at
654 least annually, by the pharmacist-in-charge and physician, and document the review.
655
656 (vii) A Class I pharmacy shall maintain a written plan for recovery from an event which
657 interrupts the ability of a pharmacist to electronically supervise the pharmacy and the
658 dispensing of prescription drugs at the Class I pharmacy. The written plan for recovery
659 shall include:
660

661 (I) a statement that prescription drugs shall not be dispensed at the Class I
662 pharmacy, if a pharmacist is not able to electronically supervise the pharmacy and the
663 dispensing of prescription drugs;

664
665 (II) procedures for response when a Class I pharmacy is experiencing downtime;
666 and

667
668 (III) procedures for the maintenance and testing of the written plan for recovery.

669
670 (viii) The pharmacy shall operate according to a written program for quality assurance
671 which:

672
673 (I) requires continuous supervision of the Class I pharmacy at all times the pharmacy
674 is open to provide pharmacy services; and

675
676 (II) establishes mechanisms and procedures to routinely test the operation of the
677 pharmacy system at a minimum of every six months and whenever any upgrade or
678 change is made to the system and documents each such activity.

679
680 **(d) Records**

681
682 (1) Every inventory or other record required to be kept under the provisions of section
683 shall be:

684
685 (A) kept by the pharmacy and be available, for at least two years from the date of such
686 inventory or record, for inspecting and copying by the board or its representative and to
687 other authorized local, state, or federal law enforcement agencies; and

688
689 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of
690 the Texas State Board of Pharmacy. If the pharmacy maintains the records in an
691 electronic format, the requested records must be provided in a mutually agreeable
692 electronic format if specifically requested by the board or its representative. Failure to
693 provide the records set out in this section, either on site or within 72 hours, constitutes
694 prima facie evidence of failure to keep and maintain records in violation of the Act.

695
696 (2) Records, except when specifically required to be maintained in original or hard-copy
697 form, may be maintained in an alternative data retention system, such as a data
698 processing system or direct imaging system provided:

699
700 (A) the records maintained in the alternative system contain all of the information
701 required on the manual record; and

702
703 (B) the data processing system is capable of producing a hard copy of the record upon
704 the request of the board, its representative, or other authorized local, state, or federal law
705 enforcement or regulatory agencies.

706
707 (3) Invoices and records of receipt may be kept at a location other than the pharmacy.
708 Any such records not kept at the pharmacy shall be supplied by the pharmacy within 72
709 hours, if requested by an authorized agent of the Texas State Board of Pharmacy.

710

711 **(4) A record of on-site visits by the pharmacist-in-charge or staff pharmacist shall be**
712 **maintained and include the following information:**

713
714 **(A) date of the visit;**

715
716 **(B) pharmacist's evaluation of findings; and**

717
718 **(C) signature of the visiting pharmacist.**

719
720
721 **(5) Records of drugs dispensed shall include logs, patient records, or other acceptable**
722 **methods for documentation. Documentation shall include:**

723
724 **(A) patient name;**

725
726 **(B) name, signature, or electronic signature of the person who provides the drug or**
727 **device;**

728
729 **(C) date provided; and**

730
731 **(D) the name of the drug or device and quantity provided.**

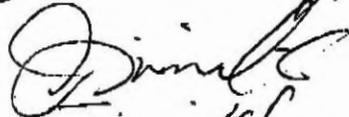
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733

Jimi Klementi, R-Ph
613 clover hill
Mansfield, TX
08/06/14

Texas State Board of Pharmacy
Austin, Texas

Dear Sir/Ma,
Here our plea to all in charge. Why will
a physician has a pharmacy in his office? I am
firmly against this idea. I thank you all for your
concerns.

Sincerely,



Jimi Klementi

Telephone: 817 715 0908
FAX : 817 419 2922
Email: klementijki@gmail.com

Jim Thompson
612 Union St
Waukegan, Ill.
8/20/28

James C. Thompson
Chicago, Ill.

Dear Sir/Mr:
I have been glad to see in Chicago today
that you have a pharmacy in Waukegan, Ill.
I am sure you will be a great help to
the community in this area. Thank you
for your service.

Very truly,
James C. Thompson
Chicago, Ill.
8/20/28