

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS PROPOSED RULES

**Short Title:** Operation

**Rule Numbers:** §291.33

**Statutory Authority:** Texas Pharmacy Act, Chapter 551-566 and 568-569, 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; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

**Purpose:** The amendments, if adopted, clarify and update the section to be consistent with other sections; require documentation of a consultation with a prescriber regarding a prescription; change the days supply for alternate labeling from 34 day supply or 100 dosage units whichever is less to a 90 day supply; and require automated checking devices to be fully automated.

**Background:** Board staff presents these amendments to update the Class A rules regarding the operation of a pharmacy.

1 **TITLE 22 EXAMINING BOARDS**  
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**  
3 **CHAPTER 291 PHARMACIES**  
4 **SUBCHAPTER B COMMUNITY PHARMACY (CLASS A)**

5  
6 **§291.33 Operational Standards**  
7

8 (a) Licensing requirements.  
9

10 (1) A Class A pharmacy shall register annually or biennially with the board on a pharmacy  
11 license application provided by the board, following the procedures specified in §291.1 of this  
12 title (relating to Pharmacy License Application).  
13

14 (2) A Class A pharmacy which changes ownership shall notify the board within ten days of the  
15 change of ownership and apply for a new and separate license as specified in §291.3 of this title  
16 (relating to Required Notifications).  
17

18 (3) A Class A pharmacy which changes location and/or name shall notify the board within ten  
19 days of the change and file for an amended license as specified in §291.3 of this title.  
20

21 (4) A Class A pharmacy owned by a partnership or corporation which changes managing  
22 officers shall notify the board in writing of the names of the new managing officers within ten  
23 days of the change, following the procedures **specified** in §291.3 of this title.  
24

25 (5) A Class A pharmacy shall notify the board in writing within ten days of closing, following the  
26 procedures **specified** in §291.5 of this title (relating to Closing a Pharmacy).  
27

28 (6) A separate license is required for each principal place of business and only one pharmacy  
29 license may be issued to a specific location.  
30

31 (7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged  
32 for the issuance and renewal of a license and the issuance of an amended license.  
33

34 (8) A Class A pharmacy, licensed under the provisions of the Act, §560.051(a)(1), which also  
35 operates another type of pharmacy which would otherwise be required to be licensed under the  
36 Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B), is not required to secure a license  
37 for such other type of pharmacy; provided, however, such licensee is required to comply with  
38 the provisions of **subchapter C of this chapter (relating to Nuclear Pharmacy (Class B))**  
39 ~~[§291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of~~  
40 ~~this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and~~  
41 ~~§291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B)],~~ to the  
42 extent such sections are applicable to the operation of the pharmacy.  
43

44 (9) A Class A ~~[(community)]~~ pharmacy engaged in the compounding of non-sterile  
45 pharmaceuticals shall comply with the provisions of §291.131 of this title (relating to Pharmacies  
46 Compounding Non-Sterile Preparations).  
47

48 (10) A Class A ~~[(community)]~~ pharmacy engaged in the compounding of sterile  
49 pharmaceuticals shall comply with the provisions of §291.133 of this title (relating to Pharmacies  
50 Compounding Sterile Preparations).  
51

52 (11) A Class A [~~Community~~] pharmacy engaged in the provision of remote pharmacy  
53 services, including storage and dispensing of prescription drugs, shall comply with the  
54 provisions of §291.121 of this title (relating to Remote Pharmacy Services).

55  
56 (12) Class A [~~Community~~] pharmacy engaged in centralized prescription dispensing and/or  
57 prescription drug or medication order processing shall comply with the provisions of §291.123 of  
58 this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or  
59 §291.125 of this title (relating to Centralized Prescription Dispensing).

60  
61 (b) Environment.

62  
63 (1) General requirements.

64  
65 (A) The pharmacy shall be arranged in an orderly fashion and kept clean. All required  
66 equipment shall be clean and in good operating condition.

67  
68 (B) A Class A pharmacy shall have a sink with hot and cold running water within the  
69 pharmacy, exclusive of restroom facilities, available to all pharmacy personnel and maintained  
70 in a sanitary condition.

71  
72 (C) A Class A pharmacy which serves the general public shall contain an area which is  
73 suitable for confidential patient counseling.

74  
75 (i) Such counseling area shall **be**:

76  
77 (I) [~~be~~] easily accessible to both patient and pharmacists and not allow patient access to  
78 prescription drugs;

79  
80 (II) [~~be~~] designed to maintain the confidentiality and privacy of the pharmacist/patient  
81 communication.

82  
83 (ii) In determining whether the area is suitable for confidential patient counseling and  
84 designed to maintain the confidentiality and privacy of the pharmacist/patient communication,  
85 the board may consider factors such as the following:

86  
87 (I) the proximity of the counseling area to the check-out or cash register area;

88  
89 (II) the volume of pedestrian traffic in and around the counseling area;

90  
91 (III) the presence of walls or other barriers between the counseling area and other areas of  
92 the pharmacy; and

93  
94 (IV) any evidence of confidential information being overheard by persons other than the  
95 patient or patient's agent or the pharmacist or agents of the pharmacist.

96  
97 (D) The pharmacy shall be properly lighted and ventilated.

98  
99 (E) The temperature of the pharmacy shall be maintained within a range compatible with the  
100 proper storage of drugs. **The** [~~the~~] temperature of the refrigerator shall be maintained within a  
101 range compatible with the proper storage of drugs requiring refrigeration.

103 (F) Animals, including birds and reptiles, shall not be kept within the pharmacy and in  
104 immediately adjacent areas under the control of the pharmacy. This provision does not apply to  
105 fish in aquariums, **service animals** ~~[guide dogs]~~ accompanying disabled persons, or animals for  
106 sale to the general public in a separate area that is inspected by local health jurisdictions.

107  
108 (2) Security.

109  
110 (A) Each pharmacist while on duty shall be responsible for the security of the prescription  
111 department, including provisions for effective control against theft or diversion of prescription  
112 drugs, and records for such drugs.

113  
114 (B) The prescription department shall be locked by key, combination or other mechanical or  
115 electronic means to prohibit unauthorized access when a pharmacist is not on-site except as  
116 provided in subparagraphs (C) and (D) of this paragraph and paragraph (3) of this subsection.  
117 The following is applicable:

118  
119 (i) If the prescription department is closed at any time when the rest of the facility is open,  
120 the prescription department must be physically or electronically secured. The security may be  
121 accomplished by means such as floor to ceiling walls; walls, partitions, or barriers at least 9 feet  
122 6 inches high; electronically monitored motion detectors; pull down sliders; or other systems or  
123 technologies that will secure the pharmacy from unauthorized entrance when the pharmacy is  
124 closed. Pharmacies licensed prior to June 1, 2009, shall be exempt from this provision unless  
125 the pharmacy changes location. Change of location shall include the relocation of the pharmacy  
126 within the licensed address. A pharmacy licensed prior to June 1, 2009 that files a change of  
127 ownership but does not change location shall be exempt from the provisions.

128  
129 (ii) The pharmacy's key, combination, or other mechanical or electronic means of locking the  
130 pharmacy may not be duplicated without the authorization of the pharmacist-in-charge or owner.

131  
132 (iii) At a minimum, the pharmacy must have a basic alarm system with off-site monitoring  
133 and perimeter and motion sensors. The pharmacy may have additional security by video  
134 surveillance camera systems.

135  
136 (C) Prior to authorizing individuals to enter the prescription department, the pharmacist-in-  
137 charge or owner may designate persons who may enter the prescription department to perform  
138 functions, other than dispensing functions or prescription processing, documented by the  
139 pharmacist-in-charge including access to the prescription department by other pharmacists,  
140 pharmacy personnel and other individuals. The pharmacy must maintain written documentation  
141 of authorized individuals other than individuals employed by the pharmacy who accessed the  
142 prescription department when a pharmacist is not on-site.

143  
144 (D) Only persons designated either by name or by title including such titles as "relief" or  
145 "floater" pharmacist, in writing by the pharmacist-in-charge may unlock the prescription  
146 department except in emergency situations. An additional key to or instructions on accessing  
147 the prescription department may be maintained in a secure location outside the prescription  
148 department for use during an emergency or as designated by the pharmacist-in-charge.

149  
150 (E) Written policies and procedures for the pharmacy's security shall be developed and  
151 implemented by the pharmacist-in-charge and/or the owner of the pharmacy. Such policies and  
152 procedures may include quarterly audits of controlled substances commonly abused or diverted;  
153 perpetual inventories for the comparison of the receipt, dispensing, and distribution of controlled

154 substances; monthly reports from the pharmacy's wholesaler(s) of controlled substances  
155 purchased by the pharmacy; opening and closing procedures; product storage and placement;  
156 and central management oversight.

157  
158 (3) Temporary absence of pharmacist.

159  
160 (A) On-site supervision by pharmacist.

161  
162 (i) If a pharmacy is staffed by only one pharmacist, the pharmacist may leave the  
163 prescription department for short periods of time without closing the prescription department and  
164 removing pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel  
165 from the prescription department provided the following conditions are met:

166  
167 (I) at least one pharmacy technician remains in the prescription department;

168  
169 (II) the pharmacist remains on-site at the licensed location of the pharmacy and is  
170 immediately available;

171  
172 (III) the pharmacist reasonably believes that the security of the prescription department will  
173 be maintained in his or her absence. If in the professional judgment of the pharmacist, the  
174 pharmacist determines that the prescription department should close during his or her absence,  
175 then the pharmacist shall close the prescription department and remove the pharmacy  
176 technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription  
177 department during his or her absence; and

178  
179 (IV) a notice is posted which includes the following information:

180  
181 (-a-) the pharmacist is on a break and the time the pharmacist will return; and

182  
183 (-b-) pharmacy technicians may begin the processing of prescription drug orders or refills  
184 brought in during the pharmacist's absence, but the prescription or refill may not be delivered to  
185 the patient or the patient's agent until the pharmacist verifies the accuracy of the prescription.

186  
187 (ii) During the time a pharmacist is absent from the prescription department, only pharmacy  
188 technicians who have completed the pharmacy's training program may perform the following  
189 duties, provided a pharmacist verifies the accuracy of all acts, tasks, and functions performed by  
190 the pharmacy technicians prior to delivery of the prescription to the patient or the patient's  
191 agent:

192  
193 (I) initiating and receiving refill authorization requests;

194  
195 (II) entering prescription data into a data processing system;

196  
197 (III) taking a stock bottle from the shelf for a prescription;

198  
199 (IV) preparing and packaging prescription drug orders (i.e., counting tablets/capsules,  
200 measuring liquids and placing them in the prescription container);

201  
202 (V) affixing prescription labels and auxiliary labels to the prescription container; and

203  
204 (VI) prepackaging and labeling prepackaged drugs.

205  
206 (iii) Upon return to the prescription department, the pharmacist shall:  
207  
208 (I) conduct a drug regimen review as specified in subsection (c)(2) of this section; and  
209  
210 (II) verify the accuracy of all acts, tasks, and functions performed by the pharmacy  
211 technicians prior to delivery of the prescription to the patient or the patient's agent.  
212  
213 (iv) An agent of the pharmacist may deliver a previously verified prescription to the patient or  
214 his or her agent provided a record of the delivery is maintained containing the following  
215 information:  
216  
217 (I) date of the delivery;  
218  
219 (II) unique identification number of the prescription drug order;  
220  
221 (III) patient's name;  
222  
223 (IV) patient's phone number or the phone number of the person picking up the prescription;  
224 and  
225  
226 (V) signature of the person picking up the prescription.  
227  
228 (v) Any prescription delivered to a patient when a pharmacist is not in the prescription  
229 department must meet the requirements for a prescription delivered to a patient as described in  
230 subsection (c)(1)(F) of this section.  
231  
232 (vi) During the times a pharmacist is absent from the prescription department a pharmacist  
233 intern shall be considered a registered pharmacy technician and may perform only the duties of  
234 a registered pharmacy technician.  
235  
236 (vii) In pharmacies with two or more pharmacists on duty, the pharmacists shall stagger their  
237 breaks and meal periods so that the prescription department is not left without a pharmacist on  
238 duty.  
239  
240 (B) Pharmacist is off-site.  
241  
242 (i) The prescription department must be secured with procedures for entry during the time  
243 that a pharmacy is not under the continuous on-site supervision of a pharmacist and the  
244 pharmacy is not open for pharmacy services.  
245  
246 (ii) Pharmacy technicians and pharmacy technician trainees may not perform any duties of a  
247 pharmacy technician or pharmacy technician trainee during the time that the pharmacist is off-  
248 site.  
249  
250 (iii) A pharmacy may use an automated storage and distribution device as specified in  
251 subsection (i) of this section for pick-up of a previously verified prescription by a patient or  
252 patient's agent, provided the following conditions are met:  
253  
254 (I) a notice is posted which includes the following information:  
255

256 (-a-) the pharmacist is off-site and not present in the pharmacy;  
257  
258 (-b-) no new prescriptions may be prepared at the pharmacy but previously verified  
259 prescriptions may be delivered to the patient or the patient's agent; and  
260  
261 (-c-) the date/time when the pharmacist will return.  
262  
263 (II) the pharmacy must maintain documentation of the absences of the pharmacist(s); and  
264  
265 (III) the prescription department is locked and secured to prohibit unauthorized entry.  
266  
267 (iv) An agent of the pharmacist may deliver a previously verified prescription to a patient or  
268 patient's agent during short periods of time when a pharmacist is off-site, provided the following  
269 conditions are met:  
270  
271 (I) short periods of time may not exceed two consecutive hours in a 24 hour period;  
272  
273 (II) a notice is posted which includes the following information:  
274  
275 (-a-) the pharmacist is off-site and not present in the pharmacy;  
276  
277 (-b-) no new prescriptions may be prepared at the pharmacy but previously verified  
278 prescriptions may be delivered to the patient or the patient's agent; and  
279  
280 (-c-) the date/time when the pharmacist will return.  
281  
282 (III) the pharmacy must maintain documentation of the absences of the pharmacist(s); and  
283  
284 (IV) the prescription department is locked and secured to prohibit unauthorized entry.  
285  
286 (v) During the time a pharmacist is absent from the prescription department and is off-site, a  
287 record of prescriptions delivered must be maintained and contain the following information:  
288  
289 (I) date and time of the delivery;  
290  
291 (II) unique identification number of the prescription drug order;  
292  
293 (III) patient's name;  
294  
295 (IV) patient's phone number or the phone number of the person picking up the prescription;  
296 and  
297  
298 (V) signature of the person picking up the prescription.  
299  
300 (vi) Any prescription delivered to a patient when a pharmacist is not on-site at the pharmacy  
301 must meet the requirements for a prescription delivered to a patient as described in subsection  
302 (c)(1)(F) of this section.  
303  
304 (c) Prescription dispensing and delivery.  
305  
306 (1) Patient counseling and provision of drug information.

307  
308 (A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's  
309 agent, information about the prescription drug or device which in the exercise of the  
310 pharmacist's professional judgment the pharmacist deems significant, such as the following:  
311  
312 (i) the name and description of the drug or device;  
313  
314 (ii) dosage form, dosage, route of administration, and duration of drug therapy;  
315  
316 (iii) special directions and precautions for preparation, administration, and use by the  
317 patient;  
318  
319 (iv) common severe side or adverse effects or interactions and therapeutic contraindications  
320 that may be encountered, including their avoidance, and the action required if they occur;  
321  
322 (v) techniques for self-monitoring of drug therapy;  
323  
324 (vi) proper storage;  
325  
326 (vii) refill information; and  
327  
328 (viii) action to be taken in the event of a missed dose.  
329  
330 (B) Such communication **shall be**:  
331  
332 (i) ~~shall be~~ provided with each new prescription drug order;  
333  
334 (ii) ~~shall be~~ provided for any prescription drug order dispensed by the pharmacy on the  
335 request of the patient or patient's agent;  
336  
337 (iii) ~~shall be~~ communicated orally in person unless the patient or patient's agent is not at  
338 the pharmacy or a specific communication barrier prohibits such oral communication;  
339  
340 (iv) ~~shall be~~ documented by recording the initials or identification code of the pharmacist  
341 providing the counseling in the prescription dispensing record as follows:  
342  
343 (I) on the original hard-copy prescription, provided the counseling pharmacist clearly  
344 records his or her initials on the prescription for the purpose of identifying who provided the  
345 counseling;  
346  
347 (II) in the pharmacy's data processing system;  
348  
349 (III) in an electronic logbook; or  
350  
351 (IV) in a hard-copy log containing the name of the patient, date of counseling, prescription  
352 number and initials or identification code of the pharmacist providing the counseling; and  
353  
354 (v) ~~shall be~~ reinforced with written information relevant to the prescription and provided to  
355 the patient or patient's agent. The following is applicable concerning this written information.  
356

357 (I) Written information must be in plain language designed for the **patient** [consumer] and  
358 printed in an easily readable font size comparable to but no smaller than ten-point Times  
359 Roman.

360  
361 (II) When a compounded **preparation** [product] is dispensed, information shall be provided  
362 for the major active ingredient(s), if available.

363  
364 (III) For new drug entities, if no written information is initially available, the pharmacist is not  
365 required to provide information until such information is available, provided:

366  
367 (-a-) the pharmacist informs the patient or the patient's agent that the product is a new  
368 drug entity and written information is not available;

369  
370 (-b-) the pharmacist documents the fact that no written information was provided; and

371  
372 (-c-) if the prescription is refilled after written information is available, such information is  
373 provided to the patient or patient's agent.

374  
375 (IV) The written information accompanying the prescription or the prescription label shall  
376 contain the statement "Do not flush unused medications or pour down a sink or drain." A drug  
377 product on a list developed by the Federal Food and Drug Administration of medicines  
378 recommended for disposal by flushing is not required to bear this statement.

379  
380 (C) Only a pharmacist may verbally provide drug information to a patient or patient's agent  
381 and answer questions concerning prescription drugs. Non-pharmacist personnel may not ask  
382 questions of a patient or patient's agent which are intended to screen and/or limit interaction  
383 with the pharmacist.

384  
385 (D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide  
386 consultation when a patient or patient's agent refuses such consultation. The pharmacist shall  
387 document such refusal for consultation.

388  
389 (E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a  
390 prescription drug order is delivered to the patient at the pharmacy, the following is applicable.

391  
392 (i) So that a patient will have access to information concerning his or her prescription, a  
393 prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as  
394 provided in subsection (b)(3) of this section.

395  
396 (ii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must  
397 meet the requirements described in subparagraph (F) of this paragraph.

398  
399 (iii) A Class A pharmacy shall make available for use by the public a current or updated  
400 **patient prescription drug information reference text or leaflets** [edition of the United States  
401 Pharmacopeia Dispensing Information, Volume II (Advice to the Patient), or another source of  
402 such information] designed for the **patient** [consumer].

403  
404 (F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a  
405 prescription drug order is delivered to the patient or his or her agent at the patient's residence or  
406 other designated location, the following is applicable.

407

408 (i) The information specified in subparagraph (A) of this paragraph shall be delivered with  
409 the dispensed prescription in writing.

410  
411 (ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local  
412 telephone service, the pharmacy shall provide a toll-free telephone line which is answered  
413 during normal business hours to enable communication between the patient and a pharmacist.  
414

415 (iii) The pharmacist shall place on the prescription container or on a separate sheet  
416 delivered with the prescription container in both English and Spanish the local and if applicable,  
417 toll-free telephone number of the pharmacy and the statement: "Written information about this  
418 prescription has been provided for you. Please read this information before you take the  
419 medication. If you have questions concerning this prescription, a pharmacist is available during  
420 normal business hours to answer these questions at (insert the pharmacy's local and toll-free  
421 telephone numbers)."  
422

423 (iv) The pharmacy shall maintain and use adequate storage or shipment containers and use  
424 shipping processes to ensure drug stability and potency. Such shipping processes shall include  
425 the use of appropriate packaging material and/or devices to ensure that the drug is maintained  
426 at an appropriate temperature range to maintain the integrity of the medication throughout the  
427 delivery process.  
428

429 (v) The pharmacy shall use a delivery system which is designed to assure that the drugs are  
430 delivered to the appropriate patient.  
431

432 (G) Except as specified in subparagraph (B) of this paragraph, in the best interest of the  
433 public health and to optimize drug therapy, upon delivery of a refill prescription, a pharmacist  
434 shall ensure that the patient or patient's agent is offered information about the refilled  
435 prescription. Either a pharmacist or other pharmacy personnel shall inform the patient or  
436 patient's agent that a pharmacist is available to discuss the patient's prescription and provide  
437 information.  
438

439 (H) A pharmacy shall post a sign no smaller than 8.5 inches by 11 inches in clear public view  
440 at all locations in the pharmacy where a patient may pick up prescriptions. The sign shall  
441 contain the following statement in a font that is easily readable: "Do you have questions about  
442 your prescription? Ask the pharmacist." Such notification shall be in both English and Spanish.  
443

444 (I) The provisions of this paragraph do not apply to patients in facilities where drugs are  
445 administered to patients by a person required to do so by the laws of the state (i.e., nursing  
446 homes).  
447

448 (2) Pharmaceutical care services.  
449

450 (A) Drug regimen review.  
451

452 (i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or  
453 at the time of dispensing a prescription drug order, review the patient's medication record. Such  
454 review shall at a minimum identify clinically significant:  
455

456 (I) known allergies;  
457

458 (II) rational therapy-contraindications;

459  
460 (III) reasonable dose and route of administration;  
461  
462 (IV) reasonable directions for use;  
463  
464 (V) duplication of therapy;  
465  
466 (VI) drug-drug interactions;  
467  
468 (VII) drug-food interactions;  
469  
470 (VIII) drug-disease interactions;  
471  
472 (IX) adverse drug reactions; and  
473  
474 (X) proper utilization, including overutilization or underutilization.  
475  
476 (ii) Upon identifying any clinically significant conditions, situations, or items listed in clause (i)  
477 of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the  
478 problem including consultation with the prescribing practitioner. The pharmacist shall document  
479 such occurrences **as specified in subparagraph (C) of this paragraph.**  
480  
481 (iii) The drug regimen review may be conducted by remotely accessing the pharmacy's  
482 electronic data base from outside the pharmacy by:  
483  
484 (I) an individual Texas licensed pharmacist employee of the pharmacy provided the  
485 pharmacy establishes controls to protect the privacy of the patient and the security of  
486 confidential records; or  
487  
488 (II) a pharmacist employed by a Class E pharmacy provided the pharmacies have entered  
489 into a written contract or agreement which outlines the services to be provided and the  
490 responsibilities and accountabilities of each pharmacy in compliance with federal and state laws  
491 and regulations.  
492  
493 (iv) **Prior to dispensing, any** [Any]-questions regarding a prescription drug order must be  
494 resolved with the prescriber and written documentation of these discussions made and  
495 maintained **as specified in subparagraph (C) of this paragraph.**  
496  
497 (B) Other pharmaceutical care services which may be provided by pharmacists include, but  
498 are not limited to, the following:  
499  
500 (i) managing drug therapy as delegated by a practitioner as allowed under the provisions of  
501 the Medical Practices **Act**;  
502  
503 (ii) administering immunizations and vaccinations under written protocol of a physician;  
504  
505 (iii) managing patient compliance programs;  
506  
507 (iv) providing preventative health care services; and  
508

509 (v) providing case management of patients who are being treated with high-risk or high-cost  
510 drugs, or who are considered "high risk" due to their age, medical condition, family history, or  
511 related concern.

512  
513 **(C) Documentation of consultation. When a pharmacist consults a prescriber as**  
514 **described in subparagraph (B) of this paragraph the pharmacist shall document on the**  
515 **hard-copy or in the pharmacy's data processing system associated with the prescription**  
516 **such occurrences and shall include the following information:**

517  
518 **(i) date the prescriber was consulted;**

519  
520 **(ii) name of the person communicating the prescriber's instructions**

521  
522 **(iii) any applicable information pertaining to the consultation; and**

523  
524 **(iv) initials or identification code of the pharmacist performing the consultation clearly**  
525 **recorded for the purpose of identifying the pharmacist who performed the consultation if**  
526 **on the information is recorded on the hard-copy prescription.**

527  
528 (3) Generic Substitution. A pharmacist may dispense a generically equivalent drug product and  
529 shall comply with the provisions of §309.3 of this title (relating to Generic Substitution).

530  
531 (4) Substitution of dosage form.

532  
533 (A) As specified in §562.002 of the Act, a pharmacist may dispense a dosage form of a drug  
534 product different from that prescribed, such as a tablet instead of a capsule or liquid instead of  
535 tablets, provided:

536  
537 (i) the patient consents to the dosage form substitution;

538  
539 (ii) the pharmacist notifies the practitioner of the dosage form substitution; and

540  
541 (iii) the dosage form so dispensed:

542  
543 (I) contains the identical amount of the active ingredients as the dosage prescribed for the  
544 patient;

545  
546 (II) is not an enteric-coated or time release product;

547  
548 (III) does not alter desired clinical outcomes;

549  
550 (B) Substitution of dosage form may not include the substitution of a product that has been  
551 compounded by the pharmacist unless the pharmacist contacts the practitioner prior to  
552 dispensing and obtains permission to dispense the compounded product.

553  
554 (5) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response  
555 to the one prescribed shall not be made without prior approval of the prescribing practitioner.  
556 This paragraph does not apply to generic substitution. For generic substitution, see the  
557 requirements of paragraph (3) of this subsection.

558

559 (A) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery,  
560 of the dispensed prescription to the patient. Such notification shall include:

- 561 (i) a description of the change;
- 562 (ii) the reason for the change;
- 563 (iii) whom to notify with questions concerning the change; and
- 564 (iv) instructions for return of the drug if not wanted by the patient.

565  
566  
567  
568  
569 (B) The pharmacy shall maintain documentation of patient notification of therapeutic drug  
570 interchange which shall include:

- 571 (i) the date of the notification;
- 572 (ii) the method of notification;
- 573 (iii) a description of the change; and
- 574 (iv) the reason for the change.

575  
576  
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580  
581 **(C) The provisions of this paragraph do not apply to prescriptions for patients in**  
582 **facilities where drugs are administered to patients by a person required to do so by the**  
583 **laws of this state if the practitioner issuing the prescription has agreed to use of a**  
584 **formulary that includes a listing of therapeutic interchanges that the practitioner has**  
585 **agreed to allow. The pharmacy must maintain a copy of the formulary including a list of**  
586 **the practitioners that have agreed to the formulary and the signature of these**  
587 **practitioners.**

588  
589 (6) Prescription containers.

590  
591 (A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-  
592 resistant container unless:

- 593 (i) the patient or the practitioner requests the prescription not be dispensed in a child-  
594 resistant container; or
- 595 (ii) the product is exempted from requirements of the Poison Prevention Packaging Act of  
596 1970.

597  
598  
599  
600 (B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an  
601 appropriate container as specified on the manufacturer's container.

602  
603 (C) Prescription containers or closures shall not be re-used. However, if a patient or patient's  
604 agent has difficulty reading or understanding a prescription label, a prescription container may  
605 be reused provided:

- 606 (i) the container is designed to provide audio-recorded information about the proper use of  
607 the prescription medication;

608  
609

- 610 (ii) the container is reused for the same patient;  
611  
612 (iii) the container is cleaned; and  
613  
614 (iv) a new safety closure is used each time the prescription container is reused.  
615  
616 (7) Labeling.  
617  
618 (A) At the time of delivery of the drug, the dispensing container shall bear a label in plain  
619 language and printed in an easily readable font size, unless otherwise specified, with at least  
620 the following information:  
621  
622 (i) name, address and phone number of the pharmacy;  
623  
624 (ii) unique identification number of the prescription that is printed in an easily readable font  
625 size comparable to but no smaller than ten-point Times Roman;  
626  
627 (iii) date the prescription is dispensed;  
628  
629 (iv) initials or an identification code of the dispensing pharmacist;  
630  
631 (v) name of the prescribing practitioner;  
632  
633 **(vi) if the prescription was signed by a pharmacist, the name of the pharmacist who**  
634 **signed the prescription for a dangerous drug under delegated authority of a physician as**  
635 **specified in Subtitle B, Chapter 157, Occupations Code;**  
636  
637 **(vii)**[(vi)] name of the patient or if such drug was prescribed for an animal, the species of the  
638 animal and the name of the owner that is printed in an easily readable font size comparable to  
639 but no smaller than ten-point Times Roman. The name of the patient's partner or family member  
640 is not required to be on the label of a drug prescribed for a partner for a sexually transmitted  
641 disease or for a patient's family members if the patient has an illness determined by the Centers  
642 for Disease Control and Prevention, the World Health Organization, or the Governor's office to  
643 be pandemic;  
644  
645 **(viii)** [(vii)] instructions for use that is printed in an easily readable font size comparable to but  
646 no smaller than ten-point Times Roman;  
647  
648 **(ix)** [(viii)] quantity dispensed;  
649  
650 **(x)** [(ix)] appropriate ancillary instructions such as storage instructions or cautionary  
651 statements such as warnings of potential harmful effects of combining the drug product with any  
652 product containing alcohol;  
653  
654 **(xi)** [(x)] if the prescription is for a Schedules II - IV controlled substance, the statement  
655 "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for  
656 whom it was prescribed";  
657  
658 **(xii)** [(xi)] if the pharmacist has selected a generically equivalent drug pursuant to the  
659 provisions of the Act, **Chapter 562** [Chapters 562 and 563], the statement "Substituted for

660 Brand Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of  
661 the brand name product prescribed;

662  
663 [~~(xii) the name of the advanced practice nurse or physician assistant and the name of the~~  
664 ~~supervising physician, if the prescription is carried out or signed by an advanced practice nurse~~  
665 ~~or physician assistant in compliance with Subtitle B, Chapter 157, Occupations Code;]~~  
666

667 [~~(xiii) the name of the pharmacist who signed the prescription for a dangerous drug under~~  
668 ~~delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code,~~  
669 ~~and the name of the supervising physician;]~~  
670

671 **(xiii)** [~~(xiv)~~] the name and strength of the actual drug product dispensed that is printed in an  
672 easily readable font size comparable to but no smaller than ten-point Times Roman, unless  
673 otherwise directed by the prescribing practitioner;

674  
675 (I) The name shall be either:

676  
677 (-a-) the brand name; or  
678

679 (-b-) if no brand name, then the generic name and name of the manufacturer or distributor  
680 of such generic drug. (The name of the manufacturer or distributor may be reduced to an  
681 abbreviation or initials, provided the abbreviation or initials are sufficient to identify the  
682 manufacturer or distributor. For combination drug products or non-sterile compounded drug  
683 **preparations** [~~products~~] having no brand name, the principal active ingredients shall be  
684 indicated on the label.)  
685

686 (II) Except as provided in clause **(xii)** [~~(xi)~~] of this subparagraph, the brand name of the  
687 prescribed drug shall not appear on the prescription container label unless it is the drug product  
688 actually dispensed.  
689

690 **(xiv)** [~~(xv)~~] if the drug is dispensed in a container other than the manufacturer's original  
691 container, the date after which the prescription should not be used or beyond-use-date. Unless  
692 otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date  
693 the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-  
694 use-date may be placed on the prescription label or on a flag label attached to the bottle. A  
695 beyond-use-date is not required on the label of a prescription dispensed to a person at the time  
696 of release from prison or jail if the prescription is for not more than a 10-day supply of  
697 medication; and  
698

699 **(xv)** [~~(xvi)~~] either on the prescription label or the written information accompanying the  
700 prescription, the statement "Do not flush unused medications or pour down a sink or drain." A  
701 drug product on a list developed by the Federal Food and Drug Administration of medicines  
702 recommended for disposal by flushing is not required to bear this statement.  
703

704 (B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type  
705 size smaller than ten-point Times Roman, the pharmacy shall provide the patient written  
706 information containing the information specified in subparagraph (A) of this paragraph in an  
707 easily readable font size comparable to but no smaller than ten-point Times Roman.  
708

709 (C) The label is not required to include the initials or identification code of the dispensing  
710 pharmacist specified in subparagraph (A) of this paragraph if the identity of the dispensing

711 pharmacist is recorded in the pharmacy's data processing system. The record of the identity of  
712 the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

713  
714 (D) The dispensing container is not required to bear the label specified in subparagraph (A) of  
715 this paragraph if:

716  
717 (i) the drug is prescribed for administration to an ultimate user who is institutionalized in a  
718 licensed health care institution (e.g., nursing home, hospice, hospital);

719  
720 (ii) no more than a **90-day supply** [~~34-day supply or 100 dosage units, whichever is less,~~] is  
721 dispensed at one time;

722  
723 (iii) the drug is not in the possession of the ultimate user prior to administration;

724  
725 (iv) the pharmacist-in-charge has determined that the institution:

726  
727 (I) maintains medication administration records which include adequate directions for use  
728 for the drug(s) prescribed;

729  
730 (II) maintains records of ordering, receipt, and administration of the drug(s); and

731  
732 (III) provides for appropriate safeguards for the control and storage of the drug(s); and

733  
734 (v) the dispensing container bears a label that adequately:

735  
736 (I) identifies the:

737  
738 (-a-) pharmacy by name and address;

739  
740 (-b-) unique identification number of the prescription;

741  
742 (-c-) name and strength of the drug dispensed;

743  
744 (-d-) name of the patient; and

745  
746 (-e-) name of the prescribing practitioner **or** [~~and~~], if applicable, the name of the advanced  
747 practice nurse, [or] physician assistant, **or pharmacist** who signed the prescription drug order;

748  
749 (II) [~~effective June 1, 2010,~~] if the drug is dispensed in a container other than the  
750 manufacturer's original container, specifies the date after which the prescription should not be  
751 used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date  
752 shall be one year from the date the drug is dispensed or the manufacturer's expiration date,  
753 whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag  
754 label attached to the bottle. A beyond-use-date is not required on the label of a prescription  
755 dispensed to a person at the time of release from prison or jail if the prescription is for not more  
756 than a 10-day supply of medication; and

757  
758 (III) sets forth the directions for use and cautionary statements, if any, contained on the  
759 prescription drug order or required by law.

760  
761 (8) Returning Undelivered Medication to Stock.

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(A) As specified in §431.021(w), Health and Safety Code, a pharmacist may not accept an unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any person after the prescription or drug has been originally dispensed, or sold except as provided in §291.8 of this title (relating to Return of Prescription Drugs). Prescriptions that have not been picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's stock for dispensing.

(B) A pharmacist shall evaluate the quality and safety of the prescriptions to be returned to stock.

(C) Prescriptions returned to stock for dispensing shall not be mixed within the manufacturer's container.

(D) Prescriptions returned to stock for dispensing should be used as soon as possible and stored in the dispensing container. The expiration date of the medication shall be the lesser of one year from the dispensing date on the prescription label or the manufacturer's expiration date if dispensed in the manufacturer's original container.

(E) At the time of dispensing, the prescription medication shall be placed in a new prescription container and not dispensed in the previously labeled container unless the label can be completely removed. However, if the medication is in the manufacturer's original container, the pharmacy label must be removed so that no confidential patient information is released.

(d) Equipment and supplies. Class A pharmacies dispensing prescription drug orders shall have the following equipment and supplies:

- (1) data processing system including a printer or comparable equipment;
  - (2) refrigerator;
  - (3) adequate supply of child-resistant, light-resistant, tight, and if applicable, glass containers;
  - (4) adequate supply of prescription, poison, and other applicable labels;
  - (5) appropriate equipment necessary for the proper preparation of prescription drug orders;
- and
- (6) metric-apothecary weight and measure conversion charts.

(e) Library. A reference library shall be maintained which includes the following in hard-copy or electronic format:

- (1) current copies of the following:
  - (A) Texas Pharmacy Act and rules;
  - (B) Texas Dangerous Drug Act and rules;
  - (C) Texas Controlled Substances Act and rules; and

813 (D) Federal Controlled Substances Act and rules (or official publication describing the  
814 requirements of the Federal Controlled Substances Act and rules);

815  
816 (2) at least one current or updated reference from each of the following categories:  
817

818 (A) **a patient prescription drug information reference text or leaflets which are**  
819 **designed for the patient and must be available to the patient;** [patient information;]

820  
821 [~~(i) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient);~~  
822 or

823  
824 —(ii) a reference text or information leaflets which provide patient information;]

825  
826 (B) [~~drug interactions;~~] a reference text on drug interactions. [~~such as Drug Interaction Facts.~~]  
827 A separate reference is not required if other references maintained by the pharmacy contain  
828 drug interaction information including information needed to determine severity or significance of  
829 the interaction and appropriate recommendations or actions to be taken;

830  
831 (C) a general information reference text, such as:

832  
833 (i) Facts and Comparisons with current supplements;

834  
835 (ii) [~~United States Pharmacopeia Dispensing Information Volume I (Drug Information for the~~  
836 ~~Healthcare Provider);~~]

837  
838 [~~(iii)] Clinical Pharmacology;~~

839  
840 **(iii)**[~~(iv)] American Hospital Formulary Service [with current supplements; or~~

841  
842 **(iv)** [~~(v)] Remington's Pharmaceutical Sciences; and~~

843  
844 (3) basic antidote information and the telephone number of the nearest Regional Poison  
845 Control Center.

846  
847 (f) Drugs.

848  
849 (1) Procurement and storage.

850  
851 (A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of  
852 drugs, but may receive input from other appropriate staff relative to such responsibility.

853  
854 (B) Prescription drugs and devices and nonprescription Schedule V controlled substances  
855 shall be stored within the prescription department or a locked storage area.

856  
857 (C) All drugs shall be stored at the proper temperature, as defined in the USP/NF and  
858 §291.15 of this title (relating to Storage of Drugs).

859  
860 (2) Out-of-date drugs or devices.

861  
862 (A) Any drug or device bearing an expiration date shall not be dispensed beyond the  
863 expiration date of the drug or device.

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(B) Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined together until such drugs or devices are disposed of properly.

(3) Nonprescription Schedule V controlled substances.

(A) Schedule V controlled substances containing codeine, dihydrocodeine, or any of the salts of codeine or dihydrocodeine may not be distributed without a prescription drug order from a practitioner.

(B) A pharmacist may distribute nonprescription Schedule V controlled substances which contain no more than 15 milligrams of opium per 29.5729 ml or per 28.35 Gm provided:

(i) such distribution is made only by a pharmacist; a nonpharmacist employee may not distribute a nonprescription Schedule V controlled substance even if under the supervision of a pharmacist; however, after the pharmacist has fulfilled professional and legal responsibilities, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist:

(ii) not more than 240 ml (eight fluid ounces), or not more than 48 solid dosage units of any substance containing opium, may be distributed to the same purchaser in any given 48-hour period without a prescription drug order;

(iii) the purchaser is at least 18 years of age; and

(iv) the pharmacist requires every purchaser not known to the pharmacist to furnish suitable identification (including proof of age where appropriate).

(C) A record of such distribution shall be maintained by the pharmacy in a bound record book. The record shall contain the following information:

(i) true name of the purchaser;

(ii) current address of the purchaser;

(iii) name and quantity of controlled substance purchased;

(iv) date of each purchase; and

(v) signature or written initials of the distributing pharmacist.

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

(g) Prepackaging of drugs.

(1) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(2) The label of a prepackaged unit shall indicate:

- 915  
916 (A) brand name and strength of the drug; or if no brand name, then the generic name,  
917 strength, and name of the manufacturer or distributor;  
918  
919 (B) facility's lot number;  
920  
921 (C) **facility's beyond use date;** ~~[expiration date;]~~ and  
922  
923 (D) quantity of the drug, if the quantity is greater than one.  
924  
925 (3) Records of prepackaging shall be maintained to show:  
926  
927 (A) name of the drug, strength, and dosage form;  
928  
929 (B) facility's lot number;  
930  
931 (C) manufacturer or distributor;  
932  
933 (D) manufacturer's lot number;  
934  
935 (E) **manufacturer's** expiration date;  
936  
937 (F) quantity per prepackaged unit;  
938  
939 (G) number of prepackaged units;  
940  
941 (H) date packaged;  
942  
943 (I) name, initials, or electronic signature of the prepacker; and  
944  
945 (J) signature, or electronic signature of the responsible pharmacist.  
946  
947 (4) Stock packages, repackaged units, and control records shall be quarantined together until  
948 checked/released by the pharmacist.  
949  
950 (h) Customized patient medication packages.  
951  
952 (1) Purpose. In lieu of dispensing two or more prescribed drug products in separate containers,  
953 a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber,  
954 provide a customized patient medication package (patient med-pak).  
955  
956 ~~[(2) Definition. A patient med-pak is a package prepared by a pharmacist for a specific patient~~  
957 ~~comprising a series of containers and containing two or more prescribed solid oral dosage~~  
958 ~~forms. The patient med-pak is so designed or each container is so labeled as to indicate the day~~  
959 ~~and time, or period of time, that the contents within each container are to be taken.]~~  
960  
961 **(2)** ~~[(3)]~~ Label.  
962  
963 (A) The patient med-pak shall bear a label stating:  
964  
965 (i) the name of the patient;

966  
967 (ii) the unique identification number for the patient med-pak itself and a separate unique  
968 identification number for each of the prescription drug orders for each of the drug products  
969 contained therein;  
970  
971 (iii) the name, strength, physical description or identification, and total quantity of each drug  
972 product contained therein;  
973  
974 (iv) the directions for use and cautionary statements, if any, contained in the prescription  
975 drug order for each drug product contained therein;  
976  
977 (v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic  
978 beverage with any drug product contained therein;  
979  
980 (vi) any storage instructions or cautionary statements required by the official compendia;  
981  
982 (vii) the name of the prescriber of each drug product;  
983  
984 (viii) the name, address, and telephone number of the pharmacy;  
985  
986 (ix) the initials or an identification code of the dispensing pharmacist;  
987  
988 (x) the date after which the prescription should not be used or beyond-use-date. Unless  
989 otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date  
990 the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained  
991 in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be  
992 placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is  
993 not required on the label of a prescription dispensed to a person at the time of release from  
994 prison or jail if the prescription is for not more than a 10-day supply of medication; and  
995  
996 (xi) either on the prescription label or the written information accompanying the prescription,  
997 the statement "Do not flush unused medications or pour down a sink or drain." A drug product  
998 on a list developed by the Federal Food and Drug Administration of medicines recommended  
999 for disposal by flushing is not required to bear this statement.  
1000  
1001 (xii) any other information, statements, or warnings required for any of the drug products  
1002 contained therein.  
1003  
1004 (B) If the patient med-pak allows for the removal or separation of the intact containers  
1005 therefrom, each individual container shall bear a label identifying each of the drug product  
1006 contained therein.  
1007  
1008 (C) The dispensing container is not required to bear the label specified in subparagraph (A) of  
1009 this paragraph if:  
1010  
1011 (i) the drug is prescribed for administration to an ultimate user who is institutionalized in a  
1012 licensed health care institution (e.g., nursing home, hospice, hospital);  
1013  
1014 (ii) no more than a **90-day supply** [~~34-day supply or 100 dosage units, whichever is less,~~] is  
1015 dispensed at one time;  
1016

1017 (iii) the drug is not in the possession of the ultimate user prior to administration;  
1018  
1019 (iv) the pharmacist-in-charge has determined that the institution:  
1020  
1021 (I) maintains medication administration records which include adequate directions for use  
1022 for the drug(s) prescribed;  
1023  
1024 (II) maintains records of ordering, receipt, and administration of the drug(s); and  
1025  
1026 (III) provides for appropriate safeguards for the control and storage of the drug(s); and  
1027  
1028 (v) the dispensing container bears a label that adequately:  
1029  
1030 (I) identifies the:  
1031  
1032 (-a-) pharmacy by name and address;  
1033  
1034 (-b-) unique identification number of the prescription;  
1035  
1036 (-c-) name and strength of each drug product dispensed;  
1037  
1038 (-d-) name of the patient; and  
1039  
1040 (-e-) name of the prescribing practitioner of each drug product, or the pharmacist ~~and if~~  
1041 ~~applicable, the name of the advanced practice nurse or physician assistant]~~ who signed the  
1042 prescription drug order;  
1043  
1044 (II) the date after which the prescription should not be used or beyond-use-date. Unless  
1045 otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date  
1046 the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained  
1047 in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be  
1048 placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is  
1049 not required on the label of a prescription dispensed to a person at the time of release from  
1050 prison or jail if the prescription is for not more than a 10-day supply of medication; and  
1051  
1052 (III) for each drug product sets forth the directions for use and cautionary statements, if  
1053 any, contained on the prescription drug order or required by law.  
1054  
1055 (4) Labeling. The patient med-pak shall be accompanied by a patient package insert, in the  
1056 event that any drug contained therein is required to be dispensed with such insert as  
1057 accompanying labeling. Alternatively, such required information may be incorporated into a  
1058 single, overall educational insert provided by the pharmacist for the total patient med-pak.  
1059  
1060 (5) Packaging. In the absence of more stringent packaging requirements for any of the drug  
1061 products contained therein, each container of the patient med-pak shall comply with official  
1062 packaging standards. Each container shall be either not reclosable or so designed as to show  
1063 evidence of having been opened.  
1064  
1065 (6) Guidelines. It is the responsibility of the dispensing pharmacist when preparing a patient  
1066 med-pak, to take into account any applicable compendial requirements or guidelines and the

1067 physical and chemical compatibility of the dosage forms placed within each container, as well as  
1068 any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

1069  
1070 (7) Recordkeeping. In addition to any individual prescription filing requirements, a record of  
1071 each patient med-pak shall be made and filed. Each record shall contain, as a minimum:

1072  
1073 (A) the name and address of the patient;

1074  
1075 (B) the unique identification number for the patient med-pak itself and a separate unique  
1076 identification number for each of the prescription drug orders for each of the drug products  
1077 contained therein;

1078  
1079 (C) the name of the manufacturer or distributor and lot number for each drug product  
1080 contained therein;

1081  
1082 (D) information identifying or describing the design, characteristics, or specifications of the  
1083 patient med-pak sufficient to allow subsequent preparation of an identical patient med-pak for  
1084 the patient;

1085  
1086 (E) the date of preparation of the patient med-pak and the beyond-use date that was  
1087 assigned;

1088  
1089 (F) any special labeling instructions; and

1090  
1091 (G) the initials or an identification code of the dispensing pharmacist.  
1092

1093 (8) The patient med-pak label is not required to include the initials or identification code of the  
1094 dispensing pharmacist specified in paragraph ~~(2) [(3)]~~(A) of this subsection if the identity of the  
1095 dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the  
1096 identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing  
1097 system.

1098  
1099 (i) Automated devices and systems.

1100  
1101 (1) Automated compounding or counting devices. If a pharmacy uses automated compounding  
1102 or counting devices:

1103  
1104 (A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated  
1105 compounding or counting device and document the calibration and verification on a routine  
1106 basis;

1107  
1108 (B) the devices may be loaded with bulk or unlabeled drugs only by a pharmacist or by  
1109 pharmacy technicians **or pharmacy technician trainees** under the direction and direct  
1110 supervision of a pharmacist;

1111  
1112 (C) the label of an automated compounding or counting device container shall indicate the  
1113 brand name and strength of the drug; or if no brand name, then the generic name, strength, and  
1114 name of the manufacturer or distributor;  
1115

1116 (D) records of loading bulk or unlabeled drugs into an automated compounding or counting  
1117 device shall be maintained to show:

- 1118 (i) name of the drug, strength, and dosage form;  
1119  
1120 (ii) manufacturer or distributor;  
1121  
1122 (iii) manufacturer's lot number;  
1123  
1124 (iv) manufacturer's expiration date;  
1125  
1126 (v) date of loading;  
1127  
1128 (vi) name, initials, or electronic signature of the person loading the automated compounding  
1129 or counting device; and  
1130  
1131 (vii) signature or electronic signature of the responsible pharmacist; and  
1132

1133 (E) the automated compounding or counting device shall not be used until a pharmacist  
1134 verifies that the system is properly loaded and affixes his or her signature to the record specified  
1135 in subparagraph (D) of this paragraph.  
1136

1137 (2) Automated pharmacy dispensing systems.  
1138

1139 (A) Authority to use automated pharmacy dispensing systems. A pharmacy may use an  
1140 automated pharmacy dispensing system to fill prescription drug orders provided that:  
1141

- 1142 (i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;  
1143  
1144 (ii) the automated pharmacy dispensing system has been tested by the pharmacy and found  
1145 to dispense accurately. The pharmacy shall make the results of such testing available to the  
1146 board [~~Board~~] upon request; and  
1147  
1148 (iii) the pharmacy will make the automated pharmacy dispensing system available for  
1149 inspection by the board for the purpose of validating the accuracy of the system.  
1150

1151 (B) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing  
1152 system to fill prescription drug orders shall operate according to a written program for quality  
1153 assurance of the automated pharmacy dispensing system which:  
1154

- 1155 (i) requires continuous monitoring of the automated pharmacy dispensing system; and  
1156  
1157 (ii) establishes mechanisms and procedures to test the accuracy of the automated  
1158 pharmacy dispensing system at least every six months and whenever any upgrade or change is  
1159 made to the system and documents each such activity.  
1160

1161 (C) Policies and procedures of operation.  
1162

1163 (i) When an automated pharmacy dispensing system is used to fill prescription drug orders,  
1164 it shall be operated according to written policies and procedures of operation. The policies and  
1165 procedures of operation shall: [~~The policies and procedures of operation shall establish~~  
1166

1167 requirements for operation of the automated pharmacy dispensing system and shall describe  
1168 policies and procedures that:]  
1169  
1170 [(I) include a description of the policies and procedures of operation;]  
1171  
1172 (I) [(II)] provide for a pharmacist's review, approval, and accountability for the transmission  
1173 of each original or new prescription drug order to the automated pharmacy dispensing system  
1174 before the transmission is made;  
1175  
1176 (II) [(III)] provide for access to the automated pharmacy dispensing system for stocking and  
1177 retrieval of medications which is limited to licensed healthcare professionals or pharmacy  
1178 technicians acting under the supervision of a pharmacist;  
1179  
1180 (III) [(IV)] require prior to use, that a pharmacist checks, verifies, and documents that the  
1181 automated pharmacy dispensing system has been accurately filled each time the system is  
1182 stocked;  
1183  
1184 (IV) [(V)] provide for an accountability record to be maintained which documents all  
1185 transactions relative to stocking and removing medications from the automated pharmacy  
1186 dispensing system;  
1187  
1188 (V) [(VI)] require a prospective drug regimen review is conducted as specified in subsection  
1189 (c)(2) of this section; and  
1190  
1191 (VI) [(VII)] establish and make provisions for documentation of a preventative maintenance  
1192 program for the automated pharmacy dispensing system.  
1193  
1194 (ii) A pharmacy which uses an automated pharmacy dispensing system to fill prescription  
1195 drug orders shall, at least annually, review its written policies and procedures, revise them if  
1196 necessary, and document the review.  
1197  
1198 (D) Recovery Plan. A pharmacy which uses an automated pharmacy dispensing system to fill  
1199 prescription drug orders shall maintain a written plan for recovery from a disaster or any other  
1200 situation which interrupts the ability of the automated pharmacy dispensing system to provide  
1201 services necessary for the operation of the pharmacy. The written plan for recovery shall  
1202 include:  
1203  
1204 (i) planning and preparation for maintaining pharmacy services when an automated  
1205 pharmacy dispensing system is experiencing downtime;  
1206  
1207 (ii) procedures for response when an automated pharmacy dispensing system is  
1208 experiencing downtime; **and**  
1209  
1210 (iii) procedures for the maintenance and testing of the written plan for recovery; ~~]; and~~  
1211  
1212 ~~—(iv) procedures for notification of the Board, each patient of the pharmacy, and other~~  
1213 ~~appropriate agencies whenever an automated pharmacy dispensing system experiences~~  
1214 ~~downtime for more than two days of operation or a period of time which significantly limits the~~  
1215 ~~pharmacy's ability to provide pharmacy services.]~~  
1216

1217 **(E)** ~~[(3)]~~ Final check of prescriptions dispensed using an automated pharmacy dispensing  
1218 system. For the purpose of §291.32**(c)(2)(D)**~~[(b)(2)]~~ of this title (relating to Personnel), a  
1219 pharmacist must perform the final check of all prescriptions prior to delivery to the patient to  
1220 ensure that the prescription is dispensed accurately as prescribed.

1221  
1222 **(i)** ~~[(A)]~~ This final check shall be considered accomplished if:

1223  
1224 **(I)** ~~[(i)]~~ a check of the final product is conducted by a pharmacist after the automated  
1225 **pharmacy dispensing** system has completed the prescription and prior to delivery to the  
1226 patient; or

1227  
1228 **(II)** ~~[(ii)]~~ the following checks are conducted by a pharmacist:

1229  
1230 **(-a-)** ~~[(+)]~~ if the automated pharmacy dispensing system contains bulk stock drugs, a  
1231 pharmacist verifies that those drugs have been accurately stocked as specified in  
1232 **subparagraph (C)(i)(III) of this paragraph** ~~[paragraph (2)(C)(i)(IV) of this subsection];~~ and

1233  
1234 **(-b-)** ~~[(+)]~~ a pharmacist checks the accuracy of the data entry of each original or new  
1235 prescription drug order entered into the automated pharmacy dispensing system.

1236  
1237 **(ii)** ~~[(B)]~~ If the final check is accomplished as specified in **clause (i)(II) of this subparagraph**  
1238 ~~[subparagraph (A)(ii) of this paragraph],~~ the following additional requirements must be met.

1239  
1240 **(I)** ~~[(i)]~~ The dispensing process must be fully automated from the time the pharmacist  
1241 releases the prescription to the automated **pharmacy dispensing** system until a completed,  
1242 labeled prescription ready for delivery to the patient is produced.

1243  
1244 **(II)** ~~[(ii)]~~ The pharmacy has conducted initial testing and has a continuous quality assurance  
1245 program which documents that the automated pharmacy dispensing system dispenses  
1246 accurately as specified in **subparagraphs (A) and (B) of this paragraph** ~~[paragraph (2)(A) and~~  
1247 ~~(B) of this subsection].~~

1248  
1249 **(III)** ~~[(iii)]~~ The automated pharmacy dispensing system documents and maintains:

1250  
1251 **(-a-)** ~~[(+)]~~ the name(s), initials, or identification code(s) of each pharmacist responsible for  
1252 the checks outlined in **clause (i)(II) of this subparagraph** ~~[subparagraph (A)(ii) of this~~  
1253 ~~paragraph];~~ and

1254  
1255 **(-b-)** ~~[(+)]~~ the name(s), initials, or identification code(s) and specific activity(ies) of each  
1256 pharmacist, ~~[or] pharmacy technician,~~ **or pharmacy technician trainee** who performs any  
1257 other portion of the dispensing process.

1258  
1259 **(IV)** ~~[(iv)]~~ The pharmacy establishes mechanisms and procedures to test the accuracy of the  
1260 automated pharmacy dispensing system at least every month rather than every six months as  
1261 specified in **subparagraph (B) of this paragraph** ~~[paragraph (2)(B) of this subsection].~~

1262  
1263 **(3)** ~~[(4)]~~ Automated checking device.

1264  
1265 ~~[(A) For the purpose of this subsection, an automated checking device is a fully automated~~  
1266 ~~device which confirms, after dispensing but prior to delivery to the patient, that the correct drug~~  
1267 ~~and strength has been labeled with the correct label for the correct patient.]~~

1268  
1269 **(A)**~~(B)~~ For the purpose of §291.32~~(c)(2)(D)~~~~(b)(2)~~ of this title, the final check of a dispensed  
1270 prescription shall be considered accomplished using an automated checking device provided:

1271  
1272 (i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or  
1273 the following checks are performed by a pharmacist:

1274  
1275 (I) the prepackaged, tamper-evident, sealed drug **or unit-of-use container, such as**  
1276 **metered dose inhalers, insulin pens, topical creams or ointments, or ophthalmics or otics**  
1277 used to fill the order is checked by a pharmacist who verifies that the drug is labeled and  
1278 packaged accurately; and

1279  
1280 (II) a pharmacist checks the accuracy of each original or new prescription drug order.

1281  
1282 (ii) the prescription is dispensed, labeled, and made ready for delivery to the patient in  
1283 compliance with Class A ~~[(Community)]~~ Pharmacy rules; and

1284  
1285 (iii) prior to delivery to the patient:

1286  
1287 (I) the automated checking device confirms that the correct drug and strength has been  
1288 labeled with the correct label for the correct patient; and

1289  
1290 (II) a pharmacist performs all other duties required to ensure that the prescription has been  
1291 dispensed safely and accurately as prescribed.

1292  
1293 **(B)** ~~[(C)]~~ If the final check is accomplished as specified in subparagraph **(A)** ~~[(B)]~~ of this  
1294 paragraph, the following additional requirements must be met.

1295  
1296 **(i) The checking process must be fully automated from the time the pharmacist**  
1297 **releases the prescription to the automated system until a completed, labeled prescription**  
1298 **ready for delivery to the patient is produced.**

1299  
1300 **(ii)** ~~[(i)]~~ The pharmacy has conducted initial testing of the automated checking device and has  
1301 a continuous quality assurance program which documents that the automated checking device  
1302 accurately confirms that the correct drug and strength has been labeled with the correct label for  
1303 the correct patient.

1304  
1305 **(iii)** ~~[(ii)]~~ The pharmacy documents and maintains:

1306  
1307 (I) the name(s), initials, or identification code(s) of each pharmacist responsible for the  
1308 checks outlined in subparagraph **(A)** ~~[(B)]~~(i) of this paragraph; and

1309  
1310 (II) the name(s) initials, or identification code(s) and specific activity(ies) of each  
1311 pharmacist or pharmacy technician who perform any other portion of the dispensing process.

1312  
1313 **(iv)** ~~[(iii)]~~ The pharmacy establishes mechanisms and procedures to test the accuracy of the  
1314 automated checking device at least monthly.

1315  
1316 **(4)** ~~[(5)]~~ Automated storage and distribution device. A pharmacy may use an automated  
storage and distribution device to deliver a previously verified prescription to a patient or

1317 patient's agent when the pharmacy is open or when the pharmacy is closed as specified in  
1318 subsection (b)(3)(B)(iii) of this section, provided:

1319

1320 (A) the device is used to deliver refills of prescription drug orders and shall not be used to  
1321 deliver new prescriptions as defined by §291.31(26) of this title (relating to Definitions);  
1322

1323 (B) the automated storage and distribution device may not be used to deliver a controlled  
1324 substance;

1325

1326 (C) drugs stored in the automated storage and distribution device are stored at proper  
1327 temperatures;

1328

1329 (D) the patient or patient's agent is given the option to use the system;

1330

1331 (E) the patient or patient's agent has access to a pharmacist for questions regarding the  
1332 prescription at the pharmacy where the automated storage and distribution device is located, by  
1333 a telephone available at the pharmacy that connects directly to another pharmacy, or by a  
1334 telephone available at the pharmacy and a posted telephone number to reach another  
1335 pharmacy;

1336

1337 (F) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

1338

1339 (G) the automated storage and distribution device has been tested by the pharmacy and  
1340 found to dispense prescriptions accurately. The pharmacy shall make the results of such testing  
1341 available to the board upon request;

1342

1343 (H) the automated storage and distribution device may be loaded with previously verified  
1344 prescriptions only by a pharmacist or by pharmacy technicians or pharmacy technician trainees  
1345 under the direction and direct supervision of a pharmacist;

1346

1347 (I) the pharmacy will make the automated storage and distribution device available for  
1348 inspection by the board;

1349

1350 (J) the automated storage and distribution device is located within the pharmacy building  
1351 whereby pharmacy staff has access to the device from within the prescription department and  
1352 patients have access to the device from outside the prescription department. The device may  
1353 not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru;

1354

1355 (K) the automated storage and distribution device is secure from access and removal of  
1356 prescription drug orders by unauthorized individuals;

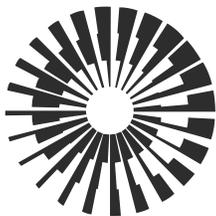
1357

1358 (L) the automated storage and distribution device has adequate security system to prevent  
1359 unauthorized access and to maintain patient confidentiality; and

1360

1361 (M) the automated storage and distribution device records a digital image of the individual  
1362 accessing the device to pick-up a prescription and such record is maintained by the pharmacy  
1363 for two years.

1364



**American Pharmaceutical Services**

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January 29, 2013

Gay Dodson, Executive Director  
Texas State Board of Pharmacy  
333 Guadalupe, Ste 3-600  
Austin, TX 78701

**RE: Substitution of Drug Product Dosage Forms – Proposal**

Dear Ms. Dodson,

Omnicare proposes the Texas State Board of Pharmacy clarify, interpret, or (if necessary) support amending Texas Statute or Texas Administrative Code. Specifically, we propose that pharmacies and pharmacists be exempt from patient consent and prescriber notification when changing a medication dosage form to another dosage form that contains the identical amount of active ingredients as the dosage prescribed for the patient.

Although contrary to current law, a licensed pharmacist could safely exercise professional judgment to change medication dosage form with the same active chemical ingredients and strength as the prescribed medication (e.g. a change from Amoxicillin capsule to Amoxicillin suspension) without patient consent or prescriber notification. This proposed practice would streamline care, limit unnecessary provider communication, and enhance patient compliance by using more appropriate medication delivery methods.

At present, pharmacists routinely request and notify prescribers before changing oral solid dosages to liquid solutions for nursing home residents who cannot swallow capsules or tablets. Compounding this issue, nursing home patients may not be able to provide consent due to cognitive impairment. In extreme circumstances, obtaining consent is virtually impossible if a patient is legally incapacitated. Residents placed on feeding tubes require a “top-down” change in medication delivery methods, which necessitates consent and notification resulting in unnecessary medication delay. These are a just a few scenarios where a proposed change in the practice would result in streamlined care and reduced delay and administrative burden on pharmacists, prescribers, and patients without altering the desired clinical outcome.

Omnicare still suggests prohibiting changes in dosage form when the physician states orally, electronically, or in his/her own handwriting “Do not substitute.” Also, it is our intention that this proposal would not apply to substitution of enteric-coated or time release products.

Thank you for your consideration regarding this matter. If requested, Omnicare can provide more information or insight into these concerns. Please contact me at the above number if you have any questions.

Respectfully,

Roberta Halverson, RPh, CGP  
Omnicare Texas State Board of Pharmacy Liaison