

## RULE ANALYSIS

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

**Short Title:** Operational Standards

**Rule Numbers:** §291.33

**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; 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, require pharmacies that ship prescription medications to ensure the medication is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

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  
9 (a) Licensing requirements.

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

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

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

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

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

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

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

34  
35 (8) A Class A pharmacy, licensed under the provisions of the Act, §560.051(a)(1), which also  
36 operates another type of pharmacy which would otherwise be required to be licensed under the  
37 Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B), is not required to secure a license  
38 for such other type of pharmacy; provided, however, such licensee is required to comply with  
39 the provisions of Subchapter C of this chapter (relating to Nuclear Pharmacy (Class B)), to the  
40 extent such sections are applicable to the operation of the pharmacy.

41  
42 (9) A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply  
43 with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile  
44 Preparations).

45  
46 (10) [~~Prior to August 31, 2014, a Class A pharmacy engaged in the compounding of sterile~~  
47 ~~preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies~~  
48 ~~Compounding Sterile Preparations).]~~

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50 **[(11) Effective August 31, 2014, a] A** Class A pharmacy shall not compound sterile  
51 preparations unless the pharmacy has applied for and obtained a Class A-S pharmacy license.

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(12) A Class A pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(13) Class A pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(b) (No change.)

(c) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

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

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

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

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

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

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

(vi) proper storage;

(vii) refill information; and

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

(B) Such communication shall be:

(i) provided to new and existing patients of a pharmacy with each new prescription drug order. A new prescription drug order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year;

(ii) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;

(iii) communicated orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication;

102 (iv) documented by recording the initials or identification code of the pharmacist providing  
103 the counseling in the prescription dispensing record as follows:

104  
105 (I) on the original hard-copy prescription, provided the counseling pharmacist clearly  
106 records his or her initials on the prescription for the purpose of identifying who provided the  
107 counseling;

108  
109 (II) in the pharmacy's data processing system;

110  
111 (III) in an electronic logbook; or

112  
113 (IV) in a hard-copy log; and

114  
115 (v) reinforced with written information relevant to the prescription and provided to the patient  
116 or patient's agent. The following is applicable concerning this written information.

117  
118 (I) Written information must be in plain language designed for the patient and printed in an  
119 easily readable font comparable to but no smaller than ten-point Times Roman. This information  
120 may be provided to the patient in an electronic format, such as by e-mail, if the patient or  
121 patient's agent requests the information in an electronic format and the pharmacy documents  
122 the request.

123  
124 (II) When a compounded preparation is dispensed, information shall be provided for the  
125 major active ingredient(s), if available.

126  
127 (III) For new drug entities, if no written information is initially available, the pharmacist is not  
128 required to provide information until such information is available, provided:

129  
130 (-a-) the pharmacist informs the patient or the patient's agent that the product is a new  
131 drug entity and written information is not available;

132  
133 (-b-) the pharmacist documents the fact that no written information was provided; and

134  
135 (-c-) if the prescription is refilled after written information is available, such information is  
136 provided to the patient or patient's agent.

137  
138 (IV) The written information accompanying the prescription or the prescription label shall  
139 contain the statement "Do not flush unused medications or pour down a sink or drain." A drug  
140 product on a list developed by the Federal Food and Drug Administration of medicines  
141 recommended for disposal by flushing is not required to bear this statement.

142  
143 (C) Only a pharmacist may verbally provide drug information to a patient or patient's agent  
144 and answer questions concerning prescription drugs. Non-pharmacist personnel may not ask  
145 questions of a patient or patient's agent which are intended to screen and/or limit interaction  
146 with the pharmacist.

147  
148 (D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide  
149 consultation when a patient or patient's agent refuses such consultation. The pharmacist shall  
150 document such refusal for consultation.

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

154 (i) So that a patient will have access to information concerning his or her prescription, a  
155 prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as  
156 provided in subsection (b)(3) of this section.  
157

158 (ii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must  
159 meet the requirements described in subparagraph (F) of this paragraph.  
160

161 (F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a  
162 prescription drug order is delivered to the patient or his or her agent at the patient's residence or  
163 other designated location, the following is applicable.  
164

165 (i) The information as specified in subparagraph (A) of this paragraph shall be delivered with  
166 the dispensed prescription in writing.  
167

168 (ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local  
169 telephone service, the pharmacy shall provide a toll-free telephone line which is answered  
170 during normal business hours to enable communication between the patient and a pharmacist.  
171

172 (iii) The pharmacist shall place on the prescription container or on a separate sheet  
173 delivered with the prescription container in both English and Spanish the local and if applicable,  
174 toll-free telephone number of the pharmacy and the statement: "Written information about this  
175 prescription has been provided for you. Please read this information before you take the  
176 medication. If you have questions concerning this prescription, a pharmacist is available during  
177 normal business hours to answer these questions at (insert the pharmacy's local and toll-free  
178 telephone numbers)."  
179

180 (iv) The pharmacy shall maintain and use adequate storage or shipment containers and use  
181 shipping processes to ensure drug stability and potency. Such shipping processes shall include  
182 the use of appropriate packaging material and/or devices, **such as temperature tags, time**  
183 **temperature strips, insulated packaging, or a combination of these,** to ensure that the drug  
184 is maintained at an appropriate temperature range to maintain the integrity of the medication  
185 throughout the delivery process.  
186

187 (v) The pharmacy shall use a delivery system, which is designed to assure that the drugs  
188 are delivered to the appropriate patient.  
189

190 (G) The provisions of this paragraph do not apply to patients in facilities where drugs are  
191 administered to patients by a person required to do so by the laws of the state (i.e., nursing  
192 homes).  
193

194 (2) Pharmaceutical care services.

195 (A) Drug regimen review.

196 (i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or  
197 at the time of dispensing a prescription drug order, review the patient's medication record. Such  
198 review shall at a minimum identify clinically significant:  
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201  
202

- 203 (I) known allergies;  
204  
205 (II) rational therapy-contraindications;  
206  
207 (III) reasonable dose and route of administration;  
208  
209 (IV) reasonable directions for use;  
210  
211 (V) duplication of therapy;  
212  
213 (VI) drug-drug interactions;  
214  
215 (VII) drug-food interactions;  
216  
217 (VIII) drug-disease interactions;  
218  
219 (IX) adverse drug reactions; and  
220  
221 (X) proper utilization, including overutilization or underutilization.  
222
- 223 (ii) Upon identifying any clinically significant conditions, situations, or items listed in clause (i)  
224 of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the  
225 problem including consultation with the prescribing practitioner. The pharmacist shall document  
226 such occurrences as specified in subparagraph (C) of this paragraph.  
227
- 228 (iii) The drug regimen review may be conducted by remotely accessing the pharmacy's  
229 electronic data base from outside the pharmacy by:  
230
- 231 (I) an individual Texas licensed pharmacist employee of the pharmacy provided the  
232 pharmacy establishes controls to protect the privacy of the patient and the security of  
233 confidential records; or  
234
- 235 (II) a pharmacist employed by a Class E pharmacy provided the pharmacies have entered  
236 into a written contract or agreement which outlines the services to be provided and the  
237 responsibilities and accountabilities of each pharmacy in compliance with federal and state laws  
238 and regulations.  
239
- 240 (iv) Prior to dispensing, any questions regarding a prescription drug order must be resolved  
241 with the prescriber and written documentation of these discussions made and maintained as  
242 specified in subparagraph (C) of this paragraph.  
243
- 244 (B) Other pharmaceutical care services which may be provided by pharmacists include, but  
245 are not limited to, the following:  
246
- 247 (i) managing drug therapy as delegated by a practitioner as allowed under the provisions of  
248 the Medical Practices Act;  
249
- 250 (ii) administering immunizations and vaccinations under written protocol of a physician;  
251
- 252 (iii) managing patient compliance programs;  
253

254 (iv) providing preventative health care services; and

255  
256 (v) providing case management of patients who are being treated with high-risk or high-cost  
257 drugs, or who are considered "high risk" due to their age, medical condition, family history, or  
258 related concern.

259  
260 (C) Documentation of consultation. When a pharmacist consults a prescriber as described in  
261 subparagraph (A) of this paragraph the pharmacist shall document on the prescription [~~hard-~~  
262 ~~copy~~] or in the pharmacy's data processing system associated with the prescription such  
263 occurrences and shall include the following information:

264  
265 (i) date the prescriber was consulted;

266  
267 (ii) name of the person communicating the prescriber's instructions;

268  
269 (iii) any applicable information pertaining to the consultation; and

270  
271 (iv) initials or identification code of the pharmacist performing the consultation clearly  
272 recorded for the purpose of identifying the pharmacist who performed the consultation [~~if on the~~  
273 ~~information is recorded on the hard-copy prescription~~].

274  
275 (3) Substitution of generically equivalent drugs or interchangeable biological products. A  
276 pharmacist may dispense a generically equivalent drug or interchangeable biological product  
277 and shall comply with the provisions of §309.3 of this title (relating to Substitution  
278 Requirements).

279  
280 (4) Substitution of dosage form.

281  
282 (A) As specified in §562.012 of the Act, a pharmacist may dispense a dosage form of a drug  
283 product different from that prescribed, such as a tablet instead of a capsule or liquid instead of  
284 tablets, provided:

285  
286 (i) the patient consents to the dosage form substitution; and

287  
288 (ii) the dosage form so dispensed:

289  
290 (I) contains the identical amount of the active ingredients as the dosage prescribed for the  
291 patient;

292  
293 (II) is not an enteric-coated or time release product;

294  
295 (III) does not alter desired clinical outcomes;

296  
297 (B) Substitution of dosage form may not include the substitution of a product that has been  
298 compounded by the pharmacist unless the pharmacist contacts the practitioner prior to  
299 dispensing and obtains permission to dispense the compounded product.

300  
301 (5) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response  
302 to the one prescribed shall not be made without prior approval of the prescribing practitioner.  
303 This paragraph does not apply to generic substitution. For generic substitution, see the  
304 requirements of paragraph (3) of this subsection.

305  
306 (A) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery,  
307 of the dispensed prescription to the patient. Such notification shall include:

- 308  
309 (i) a description of the change;  
310  
311 (ii) the reason for the change;  
312  
313 (iii) whom to notify with questions concerning the change; and  
314  
315 (iv) instructions for return of the drug if not wanted by the patient.  
316

317 (B) The pharmacy shall maintain documentation of patient notification of therapeutic drug  
318 interchange which shall include:

- 319  
320 (i) the date of the notification;  
321  
322 (ii) the method of notification;  
323  
324 (iii) a description of the change; and  
325  
326 (iv) the reason for the change.  
327

328 (C) The provisions of this paragraph do not apply to prescriptions for patients in facilities  
329 where drugs are administered to patients by a person required to do so by the laws of this state  
330 if the practitioner issuing the prescription has agreed to use of a formulary that includes a listing  
331 of therapeutic interchanges that the practitioner has agreed to allow. The pharmacy must  
332 maintain a copy of the formulary including a list of the practitioners that have agreed to the  
333 formulary and the signature of these practitioners.  
334

335 (6) Prescription containers.

336  
337 (A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-  
338 resistant container unless:

- 339  
340 (i) the patient or the practitioner requests the prescription not be dispensed in a child-  
341 resistant container; or  
342  
343 (ii) the product is exempted from requirements of the Poison Prevention Packaging Act of  
344 1970.  
345

346 (B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an  
347 appropriate container as specified on the manufacturer's container.  
348

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

- 352  
353 (i) the container is designed to provide audio-recorded information about the proper use of  
354 the prescription medication;  
355

356 (ii) the container is reused for the same patient;  
357  
358 (iii) the container is cleaned; and  
359  
360 (iv) a new safety closure is used each time the prescription container is reused.  
361  
362 (7) Labeling.  
363  
364 (A) At the time of delivery of the drug, the dispensing container shall bear a label in plain  
365 language and printed in an easily readable font size, unless otherwise specified, with at least  
366 the following information:  
367  
368 (i) name, address and phone number of the pharmacy;  
369  
370 (ii) unique identification number of the prescription that is printed in an easily readable font  
371 size comparable to but no smaller than ten-point Times Roman;  
372  
373 (iii) date the prescription is dispensed;  
374  
375 (iv) initials or an identification code of the dispensing pharmacist;  
376  
377 (v) name of the prescribing practitioner;  
378  
379 (vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed  
380 the prescription for a dangerous drug under delegated authority of a physician as specified in  
381 Subtitle B, Chapter 157, Occupations Code;  
382  
383 (vii) name of the patient or if such drug was prescribed for an animal, the species of the  
384 animal and the name of the owner that is printed in an easily readable font size comparable to  
385 but no smaller than ten-point Times Roman. The name of the patient's partner or family member  
386 is not required to be on the label of a drug prescribed for a partner for a sexually transmitted  
387 disease or for a patient's family members if the patient has an illness determined by the Centers  
388 for Disease Control and Prevention, the World Health Organization, or the Governor's office to  
389 be pandemic;  
390  
391 (viii) instructions for use that is printed in an easily readable font comparable to but no  
392 smaller than ten-point Times Roman;  
393  
394 (ix) quantity dispensed;  
395  
396 (x) appropriate ancillary instructions such as storage instructions or cautionary statements  
397 such as warnings of potential harmful effects of combining the drug product with any product  
398 containing alcohol;  
399  
400 (xi) if the prescription is for a Schedules II - IV controlled substance, the statement "Caution:  
401 Federal law prohibits the transfer of this drug to any person other than the patient for whom it  
402 was prescribed";  
403  
404 (xii) if the pharmacist has selected a generically equivalent drug or interchangeable  
405 biological product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted

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

408  
409 (xiii) the name and strength of the actual drug or biological product dispensed that is printed  
410 in an easily readable font size comparable to but no smaller than ten-point Times Roman,  
411 unless otherwise directed by the prescribing practitioner;

412  
413 (I) The name shall be either:

414  
415 (-a-) the brand name; or

416  
417 (-b-) if no brand name, then the generic drug or interchangeable biological product name  
418 and name of the manufacturer or distributor of such generic drug or interchangeable biological  
419 product. (The name of the manufacturer or distributor may be reduced to an abbreviation or  
420 initials, provided the abbreviation or initials are sufficient to identify the manufacturer or  
421 distributor. For combination drug products or non-sterile compounded drug preparations having  
422 no brand name, the principal active ingredients shall be indicated on the label.)

423  
424 (II) Except as provided in clause (xii) of this subparagraph, the brand name of the  
425 prescribed drug or biological product shall not appear on the prescription container label unless  
426 it is the drug product actually dispensed.

427  
428 (xiv) if the drug is dispensed in a container other than the manufacturer's original container,  
429 the date after which the prescription should not be used or beyond-use-date. Unless otherwise  
430 specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is  
431 dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may  
432 be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is  
433 not required on the label of a prescription dispensed to a person at the time of release from  
434 prison or jail if the prescription is for not more than a 10-day supply of medication; and

435  
436 (xv) either on the prescription label or the written information accompanying the prescription,  
437 the statement "Do not flush unused medications or pour down a sink or drain." A drug product  
438 on a list developed by the Federal Food and Drug Administration of medicines recommended  
439 for disposal by flushing is not required to bear this statement.

440  
441 (B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type  
442 size smaller than ten-point Times Roman, the pharmacy shall provide the patient written  
443 information containing the information as specified in subparagraph (A) of this paragraph in an  
444 easily readable font comparable to but no smaller than ten-point Times Roman.

445  
446 (C) The label is not required to include the initials or identification code of the dispensing  
447 pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing  
448 pharmacist is recorded in the pharmacy's data processing system. The record of the identity of  
449 the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

450  
451 (D) The dispensing container is not required to bear the label as specified in subparagraph  
452 (A) of this paragraph if:

453  
454 (i) the drug is prescribed for administration to an ultimate user who is institutionalized in a  
455 licensed health care institution (e.g., nursing home, hospice, hospital);

456

457 (ii) no more than a 90-day supply is dispensed at one time;  
458  
459 (iii) the drug is not in the possession of the ultimate user prior to administration;  
460  
461 (iv) the pharmacist-in-charge has determined that the institution:  
462  
463 (I) maintains medication administration records which include adequate directions for use  
464 for the drug(s) prescribed;  
465  
466 (II) maintains records of ordering, receipt, and administration of the drug(s); and  
467  
468 (III) provides for appropriate safeguards for the control and storage of the drug(s); and  
469  
470 (v) the dispensing container bears a label that adequately:  
471  
472 (I) identifies the:  
473  
474 (-a-) pharmacy by name and address;  
475  
476 (-b-) unique identification number of the prescription;  
477  
478 (-c-) name and strength of the drug dispensed;  
479  
480 (-d-) name of the patient; and  
481  
482 (-e-) name of the prescribing practitioner or, if applicable, the name of the advanced  
483 practice nurse, physician assistant, or pharmacist who signed the prescription drug order;  
484  
485 (II) if the drug is dispensed in a container other than the manufacturer's original container,  
486 specifies the date after which the prescription should not be used or beyond-use-date. Unless  
487 otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date  
488 the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-  
489 use-date may be placed on the prescription label or on a flag label attached to the bottle. A  
490 beyond-use-date is not required on the label of a prescription dispensed to a person at the time  
491 of release from prison or jail if the prescription is for not more than a 10-day supply of  
492 medication; and  
493  
494 (III) sets forth the directions for use and cautionary statements, if any, contained on the  
495 prescription drug order or required by law.  
496  
497 (8) Returning Undelivered Medication to Stock.  
498  
499 (A) As specified in §431.021(w), Health and Safety Code, a pharmacist may not accept an  
500 unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any  
501 person after the prescription or drug has been originally dispensed, or sold except as provided  
502 in §291.8 of this title (relating to Return of Prescription Drugs). Prescriptions that have not been  
503 picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's  
504 stock for dispensing.  
505  
506 (B) A pharmacist shall evaluate the quality and safety of the prescriptions to be returned to  
507 stock.

508  
509 (C) Prescriptions returned to stock for dispensing shall not be mixed within the manufacturer's  
510 container.

511  
512 (D) Prescriptions returned to stock for dispensing should be used as soon as possible and  
513 stored in the dispensing container. The expiration date of the medication shall be the lesser of  
514 one year from the dispensing date on the prescription label or the manufacturer's expiration  
515 date if dispensed in the manufacturer's original container.

516  
517 (E) At the time of dispensing, the prescription medication shall be placed in a new  
518 prescription container and not dispensed in the previously labeled container unless the label can  
519 be completely removed. However, if the medication is in the manufacturer's original container,  
520 the pharmacy label must be removed so that no confidential patient information is released.

521  
522 (d) – (g) (No change.)

523  
524 (h) Customized patient medication packages.

525  
526 (1) Purpose. In lieu of dispensing two or more prescribed drug products in separate containers,  
527 a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber,  
528 provide a customized patient medication package (patient med-pak).

529  
530 (2) Label.

531  
532 (A) The patient med-pak shall bear a label stating:

533  
534 (i) the name of the patient;

535  
536 (ii) the unique identification number for the patient med-pak itself and a separate unique  
537 identification number for each of the prescription drug orders for each of the drug products  
538 contained therein;

539  
540 (iii) the name, strength, physical description or identification, and total quantity of each drug  
541 product contained therein;

542  
543 (iv) the directions for use and cautionary statements, if any, contained in the prescription  
544 drug order for each drug product contained therein;

545  
546 (v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic  
547 beverage with any drug product contained therein;

548  
549 (vi) any storage instructions or cautionary statements required by the official compendia;

550  
551 (vii) the name of the prescriber of each drug product;

552  
553 (viii) the name, address, and telephone number of the pharmacy;

554  
555 (ix) the initials or an identification code of the dispensing pharmacist;

556  
557 (x) the date after which the prescription should not be used or beyond-use-date. Unless  
558 otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date

559 the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained  
560 in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be  
561 placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is  
562 not required on the label of a prescription dispensed to a person at the time of release from  
563 prison or jail if the prescription is for not more than a 10-day supply of medication;

564  
565 (xi) either on the prescription label or the written information accompanying the prescription,  
566 the statement "Do not flush unused medications or pour down a sink or drain." A drug product  
567 on a list developed by the Federal Food and Drug Administration of medicines recommended  
568 for disposal by flushing is not required to bear this statement; and

569  
570 (xii) any other information, statements, or warnings required for any of the drug products  
571 contained therein.

572  
573 (B) If the patient med-pak allows for the removal or separation of the intact containers  
574 therefrom, each individual container shall bear a label identifying each of the drug product  
575 contained therein.

576  
577 (C) The dispensing container is not required to bear the label as specified in subparagraph  
578 (A) of this paragraph if:

579  
580 (i) the drug is prescribed for administration to an ultimate user who is institutionalized in a  
581 licensed health care institution (e.g., nursing home, hospice, hospital);

582  
583 (ii) no more than a 90-day supply is dispensed at one time;

584  
585 (iii) the drug is not in the possession of the ultimate user prior to administration;

586  
587 (iv) the pharmacist-in-charge has determined that the institution:

588  
589 (I) maintains medication administration records which include adequate directions for use  
590 for the drug(s) prescribed;

591  
592 (II) maintains records of ordering, receipt, and administration of the drug(s); and

593  
594 (III) provides for appropriate safeguards for the control and storage of the drug(s); and

595  
596 (v) the dispensing container bears a label that adequately:

597  
598 (I) identifies the:

599  
600 (-a-) pharmacy by name and address;

601  
602 (-b-) [~~name of the patient; and~~]

603  
604 [~~e~~] name and strength of each drug product dispensed;

605  
606 **(-c-)** [~~d~~] name of the patient; and

607  
608 **(-d-)** [~~e~~] name of the prescribing practitioner of each drug product, or the pharmacist  
609 who signed the prescription drug order;

610  
611 (II) the date after which the prescription should not be used or beyond-use-date. Unless  
612 otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date  
613 the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained  
614 in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be  
615 placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is  
616 not required on the label of a prescription dispensed to a person at the time of release from  
617 prison or jail if the prescription is for not more than a 10-day supply of medication; and  
618

619 (III) for each drug product sets forth the directions for use and cautionary statements, if  
620 any, contained on the prescription drug order or required by law.  
621

622 (3) Labeling. The patient med-pak shall be accompanied by a patient package insert, in the  
623 event that any drug contained therein is required to be dispensed with such insert as  
624 accompanying labeling. Alternatively, such required information may be incorporated into a  
625 single, overall educational insert provided by the pharmacist for the total patient med-pak.  
626

627 (4) Packaging. In the absence of more stringent packaging requirements for any of the drug  
628 products contained therein, each container of the patient med-pak shall comply with official  
629 packaging standards. Each container shall be either not reclosable or so designed as to show  
630 evidence of having been opened.  
631

632 (5) Guidelines. It is the responsibility of the dispensing pharmacist when preparing a patient  
633 med-pak, to take into account any applicable compendial requirements or guidelines and the  
634 physical and chemical compatibility of the dosage forms placed within each container, as well as  
635 any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.  
636

637 (6) Recordkeeping. In addition to any individual prescription filing requirements, a record of  
638 each patient med-pak shall be made and filed. Each record shall contain, as a minimum:  
639

640 (A) the name and address of the patient;  
641

642 (B) the unique identification number for the patient med-pak itself and a separate unique  
643 identification number for each of the prescription drug orders for each of the drug products  
644 contained therein;  
645

646 (C) the name of the manufacturer or distributor and lot number for each drug product  
647 contained therein;  
648

649 (D) information identifying or describing the design, characteristics, or specifications of the  
650 patient med-pak sufficient to allow subsequent preparation of an identical patient med-pak for  
651 the patient;  
652

653 (E) the date of preparation of the patient med-pak and the beyond-use date that was  
654 assigned;  
655

656 (F) any special labeling instructions; and  
657

658 (G) the initials or an identification code of the dispensing pharmacist.  
659

660 (7) The patient med-pak label is not required to include the initials or identification code of the  
661 dispensing pharmacist as specified in paragraph (2)(A) of this subsection if the identity of the  
662 dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the  
663 identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing  
664 system.

665

666 (i) Automated devices and systems.

667

668 (1) Automated compounding or counting devices. If a pharmacy uses automated compounding  
669 or counting devices:

670

671 (A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated  
672 compounding or counting device and document the calibration and verification on a routine  
673 basis;

674

675 (B) the devices may be loaded with bulk or unlabeled drugs only by a pharmacist or by  
676 pharmacy technicians or pharmacy technician trainees under the direction and direct  
677 supervision of a pharmacist;

678

679 (C) the label of an automated compounding or counting device container shall indicate the  
680 brand name and strength of the drug; or if no brand name, then the generic name, strength, and  
681 name of the manufacturer or distributor;

682

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

685

686 (i) name of the drug, strength, and dosage form;

687

688 (ii) manufacturer or distributor;

689

690 (iii) manufacturer's lot number;

691

692 (iv) manufacturer's expiration date;

693

694 (v) date of loading;

695

696 (vi) name, initials, or electronic signature of the person loading the automated compounding  
697 or counting device; and

698

699 (vii) signature or electronic signature of the responsible pharmacist; and

700

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

704

705 (2) Automated pharmacy dispensing systems.

706

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

709

710 (i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

711  
712 (ii) the automated pharmacy dispensing system has been tested by the pharmacy and found  
713 to dispense accurately. The pharmacy shall make the results of such testing available to the  
714 board upon request; and

715  
716 (iii) the pharmacy will make the automated pharmacy dispensing system available for  
717 inspection by the board for the purpose of validating the accuracy of the system.

718  
719 (B) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing  
720 system to fill prescription drug orders shall operate according to a written program for quality  
721 assurance of the automated pharmacy dispensing system which:

722  
723 (i) requires continuous monitoring of the automated pharmacy dispensing system; and

724  
725 (ii) establishes mechanisms and procedures to test the accuracy of the automated  
726 pharmacy dispensing system at least every six months and whenever any upgrade or change is  
727 made to the system and documents each such activity.

728  
729 (C) Policies and procedures of operation.

730  
731 (i) When an automated pharmacy dispensing system is used to fill prescription drug orders,  
732 it shall be operated according to written policies and procedures of operation. The policies and  
733 procedures of operation shall:

734  
735 (I) provide for a pharmacist's review, approval, and accountability for the transmission of  
736 each original or new prescription drug order to the automated pharmacy dispensing system  
737 before the transmission is made;

738  
739 (II) provide for access to the automated pharmacy dispensing system for stocking and  
740 retrieval of medications which is limited to licensed healthcare professionals or pharmacy  
741 technicians acting under the supervision of a pharmacist;

742  
743 (III) require prior to use, that a pharmacist checks, verifies, and documents that the  
744 automated pharmacy dispensing system has been accurately filled each time the system is  
745 stocked;

746  
747 (IV) provide for an accountability record to be maintained which documents all transactions  
748 relative to stocking and removing medications from the automated pharmacy dispensing  
749 system;

750  
751 (V) require a prospective drug regimen review is conducted as specified in subsection  
752 (c)(2) of this section; and

753  
754 (VI) establish and make provisions for documentation of a preventative maintenance  
755 program for the automated pharmacy dispensing system.

756  
757 (ii) A pharmacy which uses an automated pharmacy dispensing system to fill prescription  
758 drug orders shall, at least annually, review its written policies and procedures, revise them if  
759 necessary, and document the review.

760

761 (D) Recovery Plan. A pharmacy which uses an automated pharmacy dispensing system to fill  
762 prescription drug orders shall maintain a written plan for recovery from a disaster or any other  
763 situation which interrupts the ability of the automated pharmacy dispensing system to provide  
764 services necessary for the operation of the pharmacy. The written plan for recovery shall  
765 include:

766  
767 (i) planning and preparation for maintaining pharmacy services when an automated  
768 pharmacy dispensing system is experiencing downtime;

769  
770 (ii) procedures for response when an automated pharmacy dispensing system is  
771 experiencing downtime; and

772  
773 (iii) procedures for the maintenance and testing of the written plan for recovery.

774  
775 (E) Final check of prescriptions dispensed using an automated pharmacy dispensing system.  
776 For the purpose of §291.32(c)(2)(D) of this title (relating to Personnel), a pharmacist must  
777 perform the final check of all prescriptions prior to delivery to the patient to ensure that the  
778 prescription is dispensed accurately as prescribed.

779  
780 (i) This final check shall be considered accomplished if:

781  
782 (I) a check of the final product is conducted by a pharmacist after the automated pharmacy  
783 dispensing system has completed the prescription and prior to delivery to the patient; or

784  
785 (II) the following checks are conducted by a pharmacist:

786  
787 (-a-) if the automated pharmacy dispensing system contains bulk stock drugs, a  
788 pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph  
789 (C)(i)(III) of this paragraph; and

790  
791 (-b-) a pharmacist checks the accuracy of the data entry of each original or new  
792 prescription drug order entered into the automated pharmacy dispensing system.

793  
794 (ii) If the final check is accomplished as specified in clause (i)(II) of this subparagraph, the  
795 following additional requirements must be met.

796  
797 (I) The dispensing process must be fully automated from the time the pharmacist releases  
798 the prescription to the automated pharmacy dispensing system until a completed, labeled  
799 prescription ready for delivery to the patient is produced.

800  
801 (II) The pharmacy has conducted initial testing and has a continuous quality assurance  
802 program which documents that the automated pharmacy dispensing system dispenses  
803 accurately as specified in subparagraphs (A) and (B) of this paragraph.

804  
805 (III) The automated pharmacy dispensing system documents and maintains:

806  
807 (-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the  
808 checks outlined in clause (i)(II) of this subparagraph; and

809

810 (-b-) the name(s), initials, or identification code(s) and specific activity(ies) of each  
811 pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other  
812 portion of the dispensing process.

813  
814 (IV) The pharmacy establishes mechanisms and procedures to test the accuracy of the  
815 automated pharmacy dispensing system at least every month rather than every six months as  
816 specified in subparagraph (B) of this paragraph.

817  
818 (3) Automated checking device.

819  
820 (A) For the purpose of §291.32(c)(2)(D) of this title, the final check of a dispensed prescription  
821 shall be considered accomplished using an automated checking device provided:

822  
823 (i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or  
824 the following checks are performed by a pharmacist:

825  
826 (I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies that  
827 the drug is labeled and packaged accurately; and

828  
829 (II) a pharmacist checks the accuracy of each original or new prescription drug order.

830  
831 (ii) the prescription is dispensed, labeled, and made ready for delivery to the patient in  
832 compliance with Class A (Community) Pharmacy rules; and

833  
834 (iii) prior to delivery to the patient:

835  
836 (I) the automated checking device confirms that the correct drug and strength has been  
837 labeled with the correct label for the correct patient; and

838  
839 (II) a pharmacist performs all other duties required to ensure that the prescription has been  
840 dispensed safely and accurately as prescribed.

841  
842 (B) If the final check is accomplished as specified in subparagraph (A) of this paragraph, the  
843 following additional requirements must be met.

844  
845 (i) The pharmacy has conducted initial testing of the automated checking device and has a  
846 continuous quality assurance program which documents that the automated checking device  
847 accurately confirms that the correct drug and strength has been labeled with the correct label for  
848 the correct patient.

849  
850 (ii) The pharmacy documents and maintains:

851  
852 (I) the name(s), initials, or identification code(s) of each pharmacist responsible for the  
853 checks outlined in subparagraph (A)(i) of this paragraph; and

854  
855 (II) the name(s) initials, or identification code(s) and specific activity(ies) of each  
856 pharmacist or pharmacy technician who perform any other portion of the dispensing process.

857  
858 (iii) The pharmacy establishes mechanisms and procedures to test the accuracy of the  
859 automated checking device at least monthly.

860

861 (4) Automated storage and distribution device. A pharmacy may use an automated storage  
862 and distribution device to deliver a previously verified prescription to a patient or patient's agent  
863 when the pharmacy is open or when the pharmacy is closed as specified in subsection  
864 (b)(3)(B)(iii) of this section, provided:

865  
866 (A) the device is used to deliver refills of prescription drug orders and shall not be used to  
867 deliver new prescriptions as defined by **§291.31(28)** [~~§291.34(29)~~] of this title (relating to  
868 Definitions);

869  
870 (B) the automated storage and distribution device may not be used to deliver a controlled  
871 substance;

872  
873 (C) drugs stored in the automated storage and distribution device are stored at proper  
874 temperatures;

875  
876 (D) the patient or patient's agent is given the option to use the system;

877  
878 (E) the patient or patient's agent has access to a pharmacist for questions regarding the  
879 prescription at the pharmacy where the automated storage and distribution device is located, by  
880 a telephone available at the pharmacy that connects directly to another pharmacy, or by a  
881 telephone available at the pharmacy and a posted telephone number to reach another  
882 pharmacy;

883  
884 (F) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

885  
886 (G) the automated storage and distribution device has been tested by the pharmacy and  
887 found to dispense prescriptions accurately. The pharmacy shall make the results of such testing  
888 available to the board upon request;

889  
890 (H) the automated storage and distribution device may be loaded with previously verified  
891 prescriptions only by a pharmacist or by pharmacy technicians or pharmacy technician trainees  
892 under the direction and direct supervision of a pharmacist;

893  
894 (I) the pharmacy will make the automated storage and distribution device available for  
895 inspection by the board;

896  
897 (J) the automated storage and distribution device is located within the pharmacy building  
898 whereby pharmacy staff has access to the device from within the prescription department and  
899 patients have access to the device from outside the prescription department. The device may  
900 not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru;

901  
902 (K) the automated storage and distribution device is secure from access and removal of  
903 prescription drug orders by unauthorized individuals;

904  
905 (L) the automated storage and distribution device has adequate security system to prevent  
906 unauthorized access and to maintain patient confidentiality; and

907  
908 (M) the automated storage and distribution device records a digital image of the individual  
909 accessing the device to pick-up a prescription and such record is maintained by the pharmacy  
910 for two years.