

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED 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.

**The Board reviewed and voted to propose the amendments during the May 3, 2016, meeting. The proposed amendments were published in the June 24, 2016, issue of the *Texas Register* at 41 TexReg 4596.**

1    **SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)**

2    **22 TAC §291.33**

3    The Texas State Board of Pharmacy proposes amendments to §291.33 concerning Operational  
4    Standards. The amendments, if adopted, update references which are no longer necessary and  
5    clarifying requirements which were duplicative.

6    Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year  
7    period the rule is in effect, there will be no fiscal implications for state or local government as a  
8    result of enforcing or administering the rule.

9    Ms. Dodson has determined that, for each year of the first five-year period the rule will be in  
10   effect, the public benefit anticipated as a result of enforcing the amendments will ensure rules are  
11   up-to-date and requirements are applicable. There is no fiscal impact for individuals, small or  
12   large businesses, or to other entities which are required to comply with this section.

13   Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,  
14   M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,  
15   Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5:00  
16   p.m., August 1, 2016.

17   The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act  
18   (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the  
19   agency to protect the public through the effective control and regulation of the practice of  
20   pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the  
21   proper administration and enforcement of the Act.

22   The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas  
23   Occupations Code.

24    **§291.33.Operational Standards.**

25    (a) Licensing requirements.

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

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

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

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

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

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

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

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

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

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

55 (10) ~~[(11)]~~ A ~~[Effective August 31, 2014, a]~~ Class A pharmacy shall not compound sterile  
56 preparations ~~[unless the pharmacy has applied for and obtained a Class A-S pharmacy license].~~

57 (11) ~~[(12)]~~ A Class A pharmacy engaged in the provision of remote pharmacy services, including  
58 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of  
59 this title (relating to Remote Pharmacy Services).

60 (12) ~~[(13)]~~ Class A pharmacy engaged in centralized prescription dispensing and/or prescription  
61 drug or medication order processing shall comply with the provisions of §291.123 of this title  
62 (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of  
63 this title (relating to Centralized Prescription Dispensing).

64 (b) (No change.)

65 (c) Prescription dispensing and delivery.

66 (1) Patient counseling and provision of drug information.

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

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

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

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

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

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

76 (vi) proper storage;

77 (vii) refill information; and

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

79 (B) Such communication shall be:

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

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

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

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

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

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

92 (III) in an electronic logbook; or

93 (IV) in a hard-copy log; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

143 (iv) The pharmacy shall maintain and use adequate storage or shipment containers and use  
144 shipping processes to ensure drug stability and potency. Such shipping processes shall include  
145 the use of appropriate packaging material and/or devices to ensure that the drug is maintained at  
146 an appropriate temperature range to maintain the integrity of the medication throughout the  
147 delivery process.

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

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

153 (2) Pharmaceutical care services.

154 (A) Drug regimen review.

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

158 (I) known allergies;

159 (II) rational therapy-contraindications;

160 (III) reasonable dose and route of administration;

- 161 (IV) reasonable directions for use;
- 162 (V) duplication of therapy;
- 163 (VI) drug-drug interactions;
- 164 (VII) drug-food interactions;
- 165 (VIII) drug-disease interactions;
- 166 (IX) adverse drug reactions; and
- 167 (X) proper utilization, including overutilization or underutilization.
- 168 (ii) Upon identifying any clinically significant conditions, situations, or items listed in clause (i)  
169 of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the problem  
170 including consultation with the prescribing practitioner. The pharmacist shall document such  
171 occurrences as specified in subparagraph (C) of this paragraph.
- 172 (iii) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic  
173 data base from outside the pharmacy by:
- 174 (I) an individual Texas licensed pharmacist employee of the pharmacy provided the pharmacy  
175 establishes controls to protect the privacy of the patient and the security of confidential records;  
176 or
- 177 (II) a pharmacist employed by a Class E pharmacy provided the pharmacies have entered into a  
178 written contract or agreement which outlines the services to be provided and the responsibilities  
179 and accountabilities of each pharmacy in compliance with federal and state laws and regulations.
- 180 (iv) Prior to dispensing, any questions regarding a prescription drug order must be resolved with  
181 the prescriber and written documentation of these discussions made and maintained as specified  
182 in subparagraph (C) of this paragraph.
- 183 (B) Other pharmaceutical care services which may be provided by pharmacists include, but are  
184 not limited to, the following:
- 185 (i) managing drug therapy as delegated by a practitioner as allowed under the provisions of the  
186 Medical Practices Act;
- 187 (ii) administering immunizations and vaccinations under written protocol of a physician;
- 188 (iii) managing patient compliance programs;
- 189 (iv) providing preventative health care services; and

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

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

197 (i) date the prescriber was consulted;

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

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

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

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

206 (4) Substitution of dosage form.

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

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

211 (ii) the dosage form so dispensed:

212 (I) contains the identical amount of the active ingredients as the dosage prescribed for the  
213 patient;

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

215 (III) does not alter desired clinical outcomes;

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

219 (5) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to  
220 the one prescribed shall not be made without prior approval of the prescribing practitioner. This

221 paragraph does not apply to generic substitution. For generic substitution, see the requirements  
222 of paragraph (3) of this subsection.

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

225 (i) a description of the change;

226 (ii) the reason for the change;

227 (iii) whom to notify with questions concerning the change; and

228 (iv) instructions for return of the drug if not wanted by the patient.

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

231 (i) the date of the notification;

232 (ii) the method of notification;

233 (iii) a description of the change; and

234 (iv) the reason for the change.

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

241 (6) Prescription containers.

242 (A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-resistant  
243 container unless:

244 (i) the patient or the practitioner requests the prescription not be dispensed in a child-resistant  
245 container; or

246 (ii) the product is exempted from requirements of the Poison Prevention Packaging Act of 1970.

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

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

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

254 (ii) the container is reused for the same patient;

255 (iii) the container is cleaned; and

256 (iv) a new safety closure is used each time the prescription container is reused.

257 (7) Labeling.

258 (A) At the time of delivery of the drug, the dispensing container shall bear a label in plain  
259 language and printed in an easily readable font size, unless otherwise specified, with at least the  
260 following information:

261 (i) name, address and phone number of the pharmacy;

262 (ii) unique identification number of the prescription that is printed in an easily readable font size  
263 comparable to but no smaller than ten-point Times Roman;

264 (iii) date the prescription is dispensed;

265 (iv) initials or an identification code of the dispensing pharmacist;

266 (v) name of the prescribing practitioner;

267 (vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the  
268 prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle  
269 B, Chapter 157, Occupations Code;

270 (vii) name of the patient or if such drug was prescribed for an animal, the species of the animal  
271 and the name of the owner that is printed in an easily readable font size comparable to but no  
272 smaller than ten-point Times Roman. The name of the patient's partner or family member is not  
273 required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or  
274 for a patient's family members if the patient has an illness determined by the Centers for Disease  
275 Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;

276 (viii) instructions for use that is printed in an easily readable font comparable to but no smaller  
277 than ten-point Times Roman;

278 (ix) quantity dispensed;

279 (x) appropriate ancillary instructions such as storage instructions or cautionary statements such  
280 as warnings of potential harmful effects of combining the drug product with any product  
281 containing alcohol;

282 (xi) if the prescription is for a Schedules II - IV controlled substance, the statement "Caution:  
283 Federal law prohibits the transfer of this drug to any person other than the patient for whom it  
284 was prescribed";

285 (xii) if the pharmacist has selected a generically equivalent drug or interchangeable biological  
286 product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted for Brand  
287 Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the  
288 brand name product prescribed;

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

292 (I) The name shall be either:

293 (-a-) the brand name; or

294 (-b-) if no brand name, then the generic drug or interchangeable biological product name and  
295 name of the manufacturer or distributor of such generic drug or interchangeable biological  
296 product. (The name of the manufacturer or distributor may be reduced to an abbreviation or  
297 initials, provided the abbreviation or initials are sufficient to identify the manufacturer or  
298 distributor. For combination drug products or non-sterile compounded drug preparations having  
299 no brand name, the principal active ingredients shall be indicated on the label.)

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

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

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

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

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

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

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

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

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

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

329 (I) maintains medication administration records which include adequate directions for use for the  
330 drug(s) prescribed;

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

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

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

334 (I) identifies the:

335 (-a-) pharmacy by name and address;

336 (-b-) unique identification number of the prescription;

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

338 (-d-) name of the patient; and

339 (-e-) name of the prescribing practitioner or, if applicable, the name of the advanced practice  
340 nurse, physician assistant, or pharmacist who signed the prescription drug order;

341 (II) if the drug is dispensed in a container other than the manufacturer's original container,  
342 specifies the date after which the prescription should not be used or beyond-use-date. Unless

343 otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the  
344 drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-  
345 date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-  
346 use-date is not required on the label of a prescription dispensed to a person at the time of release  
347 from prison or jail if the prescription is for not more than a 10-day supply of medication; and

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

350 (8) Returning Undelivered Medication to Stock.

351 (A) As specified in §431.021(w), Health and Safety Code, a pharmacist may not accept an  
352 unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any  
353 person after the prescription or drug has been originally dispensed, or sold except as provided in  
354 §291.8 of this title (relating to Return of Prescription Drugs). Prescriptions that have not been  
355 picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's  
356 stock for dispensing.

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

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

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

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

368 (d) - (g) (No change.)

369 (h) Customized patient medication packages.

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

373 (2) Label.

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

375 (i) the name of the patient;

- 376 (ii) the unique identification number for the patient med-pak itself and a separate unique  
377 identification number for each of the prescription drug orders for each of the drug products  
378 contained therein;
- 379 (iii) the name, strength, physical description or identification, and total quantity of each drug  
380 product contained therein;
- 381 (iv) the directions for use and cautionary statements, if any, contained in the prescription drug  
382 order for each drug product contained therein;
- 383 (v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic  
384 beverage with any drug product contained therein;
- 385 (vi) any storage instructions or cautionary statements required by the official compendia;
- 386 (vii) the name of the prescriber of each drug product;
- 387 (viii) the name, address, and telephone number of the pharmacy;
- 388 (ix) the initials or an identification code of the dispensing pharmacist;
- 389 (x) the date after which the prescription should not be used or beyond-use-date. Unless otherwise  
390 specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak  
391 is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak  
392 if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the  
393 prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on  
394 the label of a prescription dispensed to a person at the time of release from prison or jail if the  
395 prescription is for not more than a 10-day supply of medication;
- 396 (xi) either on the prescription label or the written information accompanying the prescription, the  
397 statement "Do not flush unused medications or pour down a sink or drain." A drug product on a  
398 list developed by the Federal Food and Drug Administration of medicines recommended for  
399 disposal by flushing is not required to bear this statement; and
- 400 (xii) any other information, statements, or warnings required for any of the drug products  
401 contained therein.
- 402 (B) If the patient med-pak allows for the removal or separation of the intact containers therefrom,  
403 each individual container shall bear a label identifying each of the drug product contained  
404 therein.
- 405 (C) The dispensing container is not required to bear the label as specified in subparagraph (A) of  
406 this paragraph if:
- 407 (i) the drug is prescribed for administration to an ultimate user who is institutionalized in a  
408 licensed health care institution (e.g., nursing home, hospice, hospital);

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

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

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

412 (I) maintains medication administration records which include adequate directions for use for the  
413 drug(s) prescribed;

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

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

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

417 (I) identifies the:

418 (-a-) pharmacy by name and address;

419 ~~{(-b-) name of the patient; and}~~

420 ~~(-b-)~~ ~~{(-c-)}~~ name and strength of each drug product dispensed;

421 ~~(-c-)~~ ~~{(-d-)}~~ name of the patient; and

422 ~~(-d-)~~ ~~{(-e-)}~~ name of the prescribing practitioner of each drug product, or the pharmacist who  
423 signed the prescription drug order;

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

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

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

437 (4) Packaging. In the absence of more stringent packaging requirements for any of the drug  
438 products contained therein, each container of the patient med-pak shall comply with official

439 packaging standards. Each container shall be either not reclosable or so designed as to show  
440 evidence of having been opened.

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

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

447 (A) the name and address of the patient;

448 (B) the unique identification number for the patient med-pak itself and a separate unique  
449 identification number for each of the prescription drug orders for each of the drug products  
450 contained therein;

451 (C) the name of the manufacturer or distributor and lot number for each drug product contained  
452 therein;

453 (D) information identifying or describing the design, characteristics, or specifications of the  
454 patient med-pak sufficient to allow subsequent preparation of an identical patient med-pak for  
455 the patient;

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

457 (F) any special labeling instructions; and

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

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

464 (i) Automated devices and systems.

465 (1) Automated compounding or counting devices. If a pharmacy uses automated compounding or  
466 counting devices:

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

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

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

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

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

479 (ii) manufacturer or distributor;

480 (iii) manufacturer's lot number;

481 (iv) manufacturer's expiration date;

482 (v) date of loading;

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

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

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

489 (2) Automated pharmacy dispensing systems.

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

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

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

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

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

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

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

505 (C) Policies and procedures of operation.

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

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

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

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

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

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

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

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

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

530 (i) planning and preparation for maintaining pharmacy services when an automated pharmacy  
531 dispensing system is experiencing downtime;

532 (ii) procedures for response when an automated pharmacy dispensing system is experiencing  
533 downtime; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

565 (3) Automated checking device.

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

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

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

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

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

575 (iii) prior to delivery to the patient:

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

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

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

582 (i) The pharmacy has conducted initial testing of the automated checking device and has a  
583 continuous quality assurance program which documents that the automated checking device  
584 accurately confirms that the correct drug and strength has been labeled with the correct label for  
585 the correct patient.

586 (ii) The pharmacy documents and maintains:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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