

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

5
6 **§291.33 Operational Standards**
7

8 (a) – (b) (No change.)
9

10 (c) Prescription dispensing and delivery.

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

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

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

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

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

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

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

23 (vi) proper storage;

24 (vii) refill information; and

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

26 (B) Such communication:

27 (i) shall be provided with each new prescription drug order;

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

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

32 (iv) effective, June 1, 2010, shall be documented by recording the initials or identification
33 code of the pharmacist providing the counseling in the prescription dispensing record on
34 either the original hard-copy prescription. in the pharmacy's data processing system or in an
35 electronic logbook; and

36 (v) shall be reinforced with written information relevant to the prescription and provided
37 to the patient or patient's agent. The following is applicable concerning this written
38 information.

39 (I) Written information must be in plain language designed for the consumer and
40 printed in an easily readable font size comparable to but no smaller than ten-point Times
41 Roman.

42 (II) When a compounded product is dispensed, information shall be provided for the
43 major active ingredient(s), if available.

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

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

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

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

51 **(IV) The written information accompanying the prescription or the prescription**
52 **label shall contain the statement "Do not flush unused medications or pour down a**

53 **sink or drain." A drug product on a list developed by the Federal Food and Drug**
54 **Administration of medicines recommended for disposal by flushing is not required to**
55 **bear this statement.**

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

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

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

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

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

71 (iii) A Class A pharmacy shall make available for use by the public a current or updated
72 edition of the United States Pharmacopeia Dispensing Information, Volume II (Advice to the
73 Patient), or another source of such information designed for the consumer.

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

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

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

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

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

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

97 (G) Except as specified in subparagraph (B) of this paragraph, in the best interest of the
98 public health and to optimize drug therapy, upon delivery of a refill prescription, a pharmacist
99 shall ensure that the patient or patient's agent is offered information about the refilled
100 prescription. Either a pharmacist or other pharmacy personnel shall inform the patient or
101 patient's agent that a pharmacist is available to discuss the patient's prescription and
102 provide information.

103 (H) A pharmacy shall post a sign no smaller than 8.5 inches by 11 inches in clear public
104 view at all locations in the pharmacy where a patient may pick up prescriptions. The sign

105 shall contain the following statement in a font that is easily readable: "Do you have
106 questions about your prescription? Ask the pharmacist." Such notification shall be in both
107 English and Spanish.

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

111

112 (2) – (6) (No Change.)

113

114 (7) Labeling.

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

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

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

121 (iii) date the prescription is dispensed;

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

123 (v) name of the prescribing practitioner;

124 (vi) name of the patient or if such drug was prescribed for an animal, the species of the
125 animal and the name of the owner that is printed in an easily readable font size comparable
126 to but no smaller than ten-point Times Roman;

127 (vii) instructions for use that is printed in an easily readable font size comparable to but
128 no smaller than ten-point Times Roman;

129 (viii) quantity dispensed;

130 (ix) appropriate ancillary instructions such as storage instructions or cautionary
131 statements such as warnings of potential harmful effects of combining the drug product with
132 any product containing alcohol;

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

136 (xi) if the pharmacist has selected a generically equivalent drug pursuant to the
137 provisions of the Act, Chapters 562 and 563, the statement "Substituted for Brand
138 Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the
139 brand name product prescribed;

140 (xii) the name of the advanced practice nurse or physician assistant, if the prescription is
141 carried out or signed by an advanced practice nurse or physician assistant in compliance
142 with Subtitle B, Chapter 157, Occupations Code;

143 (xiii) the name of the pharmacist who signed the prescription for a dangerous drug under
144 delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations
145 Code;

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

149 (l) The name shall be either:

150 (-a-) the brand name; or

151 (-b-) if no brand name, then the generic name and name of the manufacturer or
152 distributor of such generic drug. (The name of the manufacturer or distributor may be
153 reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to
154 identify the manufacturer or distributor. For combination drug products or non-sterile
155 compounded drug products having no brand name, the principal active ingredients shall be
156 indicated on the label.)

157 (II) Except as provided in clause (xi) of this subparagraph, the brand name of the
158 prescribed drug shall not appear on the prescription container label unless it is the drug
159 product actually dispensed.

160 (xv) effective June 1, 2010, if the drug is dispensed in a container other than the
161 manufacturer's original container, the date after which the prescription should not be used or
162 beyond-use-date. Unless otherwise specified by the manufacture, the beyond-use-date shall
163 be one year from the date the drug is dispensed or the manufacturer's expiration date,
164 whichever is earlier. The beyond-use-date may be placed on the prescription label or on a
165 flag label attached to the bottle. A beyond-use-date is not required on the label of a
166 prescription dispensed to a person at the time of release from prison or jail if the prescription
167 is for not more than a 10-day supply of medication; **and**

168 **(xvi) either on the prescription label or the written information accompanying the**
169 **prescription, the statement "Do not flush unused medications or pour down a sink or**
170 **drain." A drug product on a list developed by the Federal Food and Drug**
171 **Administration of medicines recommended for disposal by flushing is not required to**
172 **bear this statement.**

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

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

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

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

186 (ii) no more than a 34-day supply or 100 dosage units, whichever is less, is dispensed at
187 one time;

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

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

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

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

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

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

195 (I) identifies the:

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

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

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

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

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

202 (II) effective June 1, 2010, if the drug is dispensed in a container other than the
203 manufacturer's original container, specifies the date after which the prescription should not
204 be used or beyond-use-date. Unless otherwise specified by the manufacture, the beyond-
205 use-date shall be one year from the date the drug is dispensed or the manufacturer's
206 expiration date, whichever is earlier. The beyond-use-date may be placed on the
207 prescription label or on a flag label attached to the bottle. A beyond-use-date is not required

208 on the label of a prescription dispensed to a person at the time of release from prison or jail
209 if the prescription is for not more than a 10-day supply of medication; and
210 (III) sets forth the directions for use and cautionary statements, if any, contained on the
211 prescription drug order or required by law.
212
213 (d) – (g) (No change.)
214
215 (h) Customized patient medication packages.
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217 (1) – (2) (No change.)
218
219 (3) Label.
220
221 (A) The patient med-pak shall bear a label stating:
222
223 (i) the name of the patient;
224
225 (ii) the unique identification number for the patient med-pak itself and a separate unique
226 identification number for each of the prescription drug orders for each of the drug products
227 contained therein;
228
229 (iii) the name, strength, physical description or identification, and total quantity of each
230 drug product contained therein;
231
232 (iv) the directions for use and cautionary statements, if any, contained in the prescription
233 drug order for each drug product contained therein;
234
235 (v) if applicable, a warning of the potential harmful effect of combining any form of
236 alcoholic beverage with any drug product contained therein;
237
238 (vi) any storage instructions or cautionary statements required by the official compendia;
239
240 (vii) the name of the prescriber of each drug product;
241
242 (viii) the date of preparation of the patient med-pak and the beyond-use date assigned to
243 the patient med-pak (which such beyond-use date shall not be later than 60 days from the
244 date of preparation);
245
246 (ix) the name, address, and telephone number of the pharmacy;
247
248 (x) the initials or an identification code of the dispensing pharmacist;
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250 (xi) effective June 1, 2010, the date after which the prescription should not be used or
251 beyond-use-date. Unless otherwise specified by the manufacture, the beyond-use-date shall
252 be one year from the date the med-pak is dispensed or the earliest manufacturer's
253 expiration date for a product contained in the med-pack if it is less than one-year from the
254 date dispensed. The beyond-use-date may be placed on the prescription label or on a flag
255 label attached to the bottle. A beyond-use-date is not required on the label of a prescription
256 dispensed to a person at the time of release from prison or jail if the prescription is for not
257 more than a 10-day supply of medication; and
258

259 (xii) either on the prescription label or the written information accompanying the
260 prescription, the statement "Do not flush unused medications or pour down a sink or
261 drain." A drug product on a list developed by the Federal Food and Drug
262 Administration of medicines recommended for disposal by flushing is not required to
263 bear this statement.
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265 (xiii) ~~[(xii)]~~ any other information, statements, or warnings required for any of the drug
266 products contained therein.

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268 (B) – (C) (No change.)

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270 (4) – (8) (No change.)

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272 (i) (No change.)

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER F NON-RESIDENT PHARMACY (CLASS E)

5
6 **§291.104 Operational Standards**

7
8 (a) (No change.)

9
10 (b) Prescription dispensing and delivery.

11
12 (1) – (2) (No change.)

13
14 (3) Patient counseling and provision of drug information.

15
16 (A) (No change.)

17
18 (B) Such communication:

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20 (i) – (iii) (No change.)

21
22 (iv) shall be reinforced with written information. The following is applicable concerning
23 this written information:

24
25 (I) Written information designed for the consumer, such as the USP DI patient
26 information leaflets, shall be provided.

27
28 (II) When a compounded product is dispensed, information shall be provided for the
29 major active ingredient(s), if available.

30
31 (III) For new drug entities, if no written information is initially available, the pharmacist is
32 not required to provide information until such information is available, provided:

33
34 (-a-) the pharmacist informs the patient or the patient's agent that the product is a new
35 drug entity and written information is not available;

36
37 (-b-) the pharmacist documents the fact that no written information was provided; and

38
39 (-c-) if the prescription is refilled after written information is available, such information
40 is provided to the patient or patient's agent.

41
42 **(IV) The written information accompanying the prescription or the prescription**
43 **label shall contain the statement "Do not flush unused medications or pour down a**
44 **sink or drain." A drug product on a list developed by the Federal Food and Drug**
45 **Administration of medicines recommended for disposal by flushing is not required to**
46 **bear this statement.**

47
48 (C) – (H) (No change.)

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50 (4) Labeling. At the time of delivery, the dispensing container shall bear a label that
51 contains the following information:

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(A) the name, physical address, and phone number of the pharmacy,

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

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

(D) ~~[(C)]~~ any other information that is required by the pharmacy or drug laws or rules in the state in which the pharmacy is located.

(c) – (f) (No change.)