

RULE ANALYSIS

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

Short Title: Patient Counseling Requirements

Rule Numbers: §§291.31, 291.33

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, Occupations Code:

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

Purpose: The amendments, if adopted, updated the definition of a new prescription drug order; updated the patient counseling requirements allowing written information about a medication to be provided to patients electronically, eliminate the requirement that the pharmacy have a patient prescription drug information reference text or leaflets available for patients, eliminate the requirement that a patient is offered information about refilled prescriptions, and eliminate the sign regarding the availability of a pharmacist to ask questions.

1 TEXAS ADMINISTRATIVE CODE
2 TITLE 22. EXAMINING BOARDS
3 PART 15. TEXAS STATE BOARD OF PHARMACY
4 CHAPTER 291. PHARMACIES
5 SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)
6

7 **§291.31. Definitions.**
8

9 The following words and terms, when used in this subchapter, shall have the following
10 meanings, unless the context clearly indicates otherwise.

11
12 (1) – (28) (No change.)

13
14 (29) New prescription drug order – A prescription drug order that:
15 ~~_____ (A) has not been dispensed to the patient in the same strength and dosage~~
16 ~~form by this pharmacy within the last year. [;~~
17 ~~_____ (B) is transferred from another pharmacy; and/or~~
18 ~~_____ (C) is a discharge prescription drug order. (Note: furlough prescription~~
19 ~~drug orders are not considered new prescription drug orders.)]~~
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21 (30) – (32) (No change.)

22
23 (33) Patient counseling – Communication by the pharmacist of information to the
24 patient or patient's agent in order to improve therapy by ensuring proper use of drugs and
25 devices.

26
27 (34) – (47) (No change.)
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29

30 **§291.33. Operational Standards**
31

32 (a) (No change.)

33
34 (b) Environment.

35 (1) General requirements.

36
37 (A) – (B) (No change.)

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

40 (i) Such counseling area shall be:

41 (I) easily accessible to both patient and pharmacists and not
42 allow patient access to prescription drugs; **and**

43 (II) designed to maintain the confidentiality and privacy of the
44 pharmacist/patient communication.

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

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

50 (II) the volume of pedestrian traffic in and around the
51 counseling area;

52 (III) the presence of walls or other barriers between the
53 counseling area and other areas of the pharmacy; and
54 (IV) any evidence of confidential information being overheard
55 by persons other than the patient or patient's agent or the pharmacist or agents of the
56 pharmacist.

57
58 (D) – (G) (No change.)

59
60 (2) – (3) (No change.)

61
62 (c) Prescription dispensing and delivery.

63
64 (1) Patient counseling and provision of drug information.

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

68 (i) ~~the~~ name and description of the drug or device;
69 (ii) dosage form, dosage, route of administration, and duration of drug
70 therapy;
71 (iii) special directions and precautions for preparation, administration,
72 and use by the patient;
73 (iv) common severe side or adverse effects or interactions and
74 therapeutic contraindications that may be encountered, including their avoidance, and the action
75 required if they occur;

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

77 (vi) proper storage;

78 (vii) refill information; and

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

80 (B) Such communication shall be:

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

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

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

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

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

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

96 (III) in an electronic logbook; or

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

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

101 (I) Written information must be in plain language designed for
102 the patient and printed in an easily readable font size comparable to but no smaller than ten-

point Times Roman. **This information may be provided to the patient in an electronic format, such as by e-mail, if the patient or patient's agent request the information in an electronic format and the pharmacy documents the request.**

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

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

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

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

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

(IV) The written information accompanying the prescription or the prescription label shall contain 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.

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

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

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

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

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

~~[(iii) — A Class A pharmacy shall make available for use by the public a current or updated patient prescription drug information reference text or leaflets designed for the patient.]~~

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

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

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

(iii) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and if applicable, toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist

154 is available during normal business hours to answer these questions at (insert the pharmacy's
155 local and toll-free telephone numbers)."

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

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

163 (G) ~~[Except as specified in subparagraph (B) of this paragraph, in the best
164 interest of the public health and to optimize drug therapy, upon delivery of a refill prescription, a
165 pharmacist shall ensure that the patient or patient's agent is offered information about the
166 refilled prescription. Either a pharmacist or other pharmacy personnel shall inform the patient or
167 patient's agent that a pharmacist is available to discuss the patient's prescription and provide
168 information.]~~

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

174 ~~[(I)]~~ The provisions of this paragraph do not apply to patients in facilities
175 where drugs are administered to patients by a person required to do so by the laws of the state
176 (i.e., nursing homes).

177 (2) Pharmaceutical care services.

178 (A) Drug regimen review.

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

- 182 (I) known allergies;
- 183 (II) rational therapy-contraindications;
- 184 (III) reasonable dose and route of administration;
- 185 (IV) reasonable directions for use;
- 186 (V) duplication of therapy;
- 187 (VI) drug-drug interactions;
- 188 (VII) drug-food interactions;
- 189 (VIII) drug-disease interactions;
- 190 (IX) adverse drug reactions; and
- 191 (X) proper utilization, including overutilization or

192 underutilization.

193 (ii) Upon identifying any clinically significant conditions, situations, or
194 items listed in clause (i) of this subparagraph, the pharmacist shall take appropriate steps to
195 avoid or resolve the problem including consultation with the prescribing practitioner. The
196 pharmacist shall document such occurrences as specified in subparagraph (C) of this
197 paragraph.

198 (iii) The drug regimen review may be conducted by remotely
199 accessing the pharmacy's electronic data base from outside the pharmacy by:

200 (I) an individual Texas licensed pharmacist employee of the
201 pharmacy provided the pharmacy establishes controls to protect the privacy of the patient and
202 the security of confidential records; or

203 (II) a pharmacist employed by a Class E pharmacy provided
204 the pharmacies have entered into a written contract or agreement which outlines the services to

205 be provided and the responsibilities and accountabilities of each pharmacy in compliance with
206 federal and state laws and regulations.

207 (iv) Prior to dispensing, any questions regarding a prescription drug
208 order must be resolved with the prescriber and written documentation of these discussions
209 made and maintained as specified in subparagraph (C) of this paragraph.

210 (B) Other pharmaceutical care services which may be provided by
211 pharmacists include, but are not limited to, the following:

212 (i) managing drug therapy as delegated by a practitioner as allowed
213 under the provisions of the Medical Practices Act;

214 (ii) administering immunizations and vaccinations under written
215 protocol of a physician;

216 (iii) managing patient compliance programs;

217 (iv) providing preventative health care services; and

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

221 (C) Documentation of consultation. When a pharmacist consults a prescriber
222 as described in subparagraph (A) of this paragraph the pharmacist shall document on the hard-
223 copy or in the pharmacy's data processing system associated with the prescription such
224 occurrences and shall include the following information:

225 (i) date the prescriber was consulted;

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

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

228 (iv) initials or identification code of the pharmacist performing the

229 consultation clearly recorded for the purpose of identifying the pharmacist who performed the
230 consultation if on the information is recorded on the hard-copy prescription.

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232

233 (3) – (8) No change.)

234

235 (d) – (i) (No change.)