

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 **22 TAC §291.33**  
7

8 The Texas State Board of Pharmacy proposes amendments to §291.33 concerning  
9 Operational Standards. The amendments, if adopted, clarify that prescription labels and  
10 written information provided to consumers must be printed in a type-size no smaller than 10-  
11 point Times Roman and clarify that the prescription label is not required to include the  
12 identification code or initials of the dispensing pharmacist if the information is stored in the  
13 pharmacy's data processing system.

14  
15 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year  
16 period the rule is in effect, there will be no fiscal implications for state or local government as  
17 a result of enforcing or administering the rule.

18  
19 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in  
20 effect, the public benefit anticipated as a result of enforcing the rule will be to ensure that  
21 only qualified individuals are allowed to practice pharmacy. There is no fiscal impact for  
22 individuals, small or large businesses or to other entities which are required to comply with  
23 this section.

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25 Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S.,  
26 Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,  
27 Suite 3-600, Austin, Texas 78701, FAX (512) 305-8082. Comments must be received by 5  
28 p.m., January 30, 2009.

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30 The amendments are proposed under §551.002, §554.051, §562.006, and §562.0061 of the  
31 Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The  
32 Board interprets §551.002 as authorizing the agency to protect the public through the  
33 effective control and regulation of the practice of pharmacy. The Board interprets  
34 §554.051(a) as authorizing the agency to adopt rules for the proper administration and  
35 enforcement of the Act. The Board interprets §562.006 and §562.0061 as authorizing the  
36 agency to adopt rules regarding the prescription label and written information provided to  
37 consumers.

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39 The statutes affected by this rule: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569,  
40 Texas Occupations Code.

41  
42 §291.33. Operational Standards.  
43

44  
45 (a) - (b) (No change.)  
46

47 (c) Prescription dispensing and delivery.  
48

49 (1) Patient counseling and provision of drug information.  
50

51 (A) (No change.)  
52

1 (B) Such communication:  
2  
3 (i) - (iv) (No change.)  
4  
5 (v) shall be reinforced with written information relevant to the prescription and provided to  
6 the patient or patient's agent. The following is applicable concerning this written information.  
7  
8 (I) Written information must be in plain language designed for the consumer and printed in a  
9 type size no smaller than ten-point Times Roman. [~~easily readable font size.~~]  
10  
11 (II) - (III) (No change.)  
12  
13 (C) - (I) (No change.)  
14  
15 (2) - (6) (No change.)  
16  
17 (7) Labeling.  
18  
19 (A) At the time of delivery of the drug, the dispensing container shall bear a label in plain  
20 language and printed in a type size no smaller than ten-point Times Roman [~~an easily~~  
21 ~~readable font size~~] with at least the following information:  
22  
23 (i) - (xiii) (No change.)  
24  
25 (B) If the prescription label required in subparagraph (A) of this paragraph is printed in a  
26 type size smaller than 10-point Times Roman, the pharmacy shall provide the patient written  
27 information containing the information specified in subparagraph (A) of this paragraph in a  
28 type size no smaller than ten-point Times Roman.  
29  
30 (C) The label is not required to include the initials or identification code of the dispensing  
31 pharmacist specified in subparagraph (A) of this paragraph if the identity of the dispensing  
32 pharmacist is recorded in the pharmacy's data processing system. The record of the identity  
33 of the dispensing pharmacist shall not be altered in the pharmacy's date processing system.  
34  
35 (D) [~~(B)~~] The dispensing container is not required to bear the label specified in subparagraph  
36 (A) of this paragraph if:  
37  
38 (i) the drug is prescribed for administration to an ultimate user who is institutionalized in a  
39 licensed health care institution (e.g., nursing home, hospice, hospital);  
40  
41 (ii) no more than a 34-day supply or 100 dosage units, whichever is less, is dispensed at  
42 one time;  
43  
44 (iii) the drug is not in the possession of the ultimate user prior to administration;  
45  
46 (iv) the pharmacist-in-charge has determined that the institution:  
47  
48 (I) maintains medication administration records which include adequate directions for use for  
49 the drug(s) prescribed;  
50  
51 (II) maintains records of ordering, receipt, and administration of the drug(s); and  
52

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

2  
3 (v) the dispensing container bears a label that adequately:

4  
5 (I) identifies the:

6  
7 (-a-) pharmacy by name and address;

8  
9 (-b-) unique identification number of the prescription;

10  
11 (-c-) name and strength of the drug dispensed;

12  
13 (-d-) name of the patient;

14  
15 (-e-) name of the prescribing practitioner and, if applicable, the name of the advanced  
16 practice nurse or physician assistant who signed the prescription drug order; and

17  
18 (II) sets forth the directions for use and cautionary statements, if any, contained on the  
19 prescription drug order or required by law.

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21 (d) - (i) (No change.)

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23 This agency hereby certifies that the proposal has been reviewed by legal counsel and  
24 found to be within the agency's legal authority to adopt.

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26 Filed with the Office of the Secretary of State on December 15, 2008.

27  
28 TRD-200806501

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30 Gay Dodson, R.Ph.

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32 Executive Director/Secretary

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34 Texas State Board of Pharmacy

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36 Earliest possible date of adoption: January 25, 2009

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38 For further information, please call: (512) 305-8028

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