

January 29, 2009

Allison Benz, R.Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701

RE: Proposed changes to 22 TAC §291.33 (c)(1)(B)(v)(I) & (c)(7)(A-B)

Dear Ms. Benz:

On behalf of the approximately 2,648 chain pharmacies operating in the state of Texas, the National Association of Chain Drug Stores (NACDS) thanks the Texas State Board of Pharmacy ("Board") for the opportunity to comment on proposed new font size requirements for prescription container labels and for written drug information provided to patients.

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P.O. Box 1417-D49
Alexandria, Virginia
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Proposed font size requirements for information printed on prescription labels

Under 22 TAC §291.33 (c)(7)(A-B), the Board is proposing to require that dispensing containers bear a label printed in a type size no smaller than ten-point Times Roman. Alternatively, if the label printing is smaller than ten-point Times Roman, pharmacies must then provide additional written information listing what is otherwise required to be on the label. Considering all of the elements that are required to be on the prescription label under 22 TAC §291.33 (c)(7)(A), it would be impossible to include all of these elements using ten-point Times Roman font. Pharmacies would have no other option but to provide duplicative, accompanying written information with every prescription dispensed. Notably, such information would be in addition to materials provided to patients in accordance with FDA guidelines, including Consumer Medication Information (which typically includes the information that is on the prescription label); Medication Guides (which can 20 pages or more in some cases); Patient Package Inserts; and Consumer Information Sheets *and* any additional written drug information that must be provided to patients under 22 TAC §291.33 (c)(1). There is concern that these materials already contain voluminous amount of information and are overwhelming for many patients. We are concerned that adding to these would overload patients with redundant written materials, which would reduce the likelihood that patients will actually read what written information is provided to them by the pharmacist.

Presumably, the Board's intent in proposing these rule revisions is to ensure that patients are able to clearly read the important information printed on their prescription labels, making it easier for patients to check that they have received the proper drug and can read the drug directions for use. We believe that this could be accomplished more effectively by requiring that where practical, key elements be printed in ten-point Times Roman font;

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where it would not otherwise be possible to fit the key elements on the prescription label if ten-point Times Roman font were used, the rule should allow for key elements to be printed in an appropriate sized font so as to ensure that key information fits on the label. To that end, we suggest the following amendments to 22 TAC §291.33 (c)(7)(A):

(A) At the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed ~~in a type size no smaller than ten-point Times Roman~~ [an easily readable font size-] with at least the following information:

...

(ii) unique identification number of the prescription, *which shall be printed on the label in ten-point Times Roman font or in the maximum font size which will allow the unique identification number and the other required elements to appear on the label;*

...

(vi) name of the patient or if such drug was prescribed for an animal, the species of the animal and the name of the owner, *which shall be printed on the label in ten-point Times Roman font or in the maximum font size which will allow the patient name and the other required elements to appear on the label;*

(vii) instructions for use, *which shall be printed on the label in ten-point Times Roman font or in the maximum font size which will allow the instructions for use and the other required elements to appear on the label;*

...

(xiii) the name and strength of the actual drug product dispensed, unless otherwise directed by the prescribing practitioner, *which shall be printed on the label in ten-point Times Roman font or in the maximum font size which will allow the drug name and strength and the other required elements to appear on the label.*

~~(B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type size smaller than 10-point Times Roman, the pharmacy shall provide the patient written information containing the information specified in subparagraph (A) of this paragraph in a type size no smaller than ten-point Times Roman.~~

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

Proposed font size requirements for written drug information provided to patients

Under 22 TAC §291.33 (c)(1)(B)(v)(I), the Board is proposing to require that the written drug information provided to patients along with dispensed prescriptions be printed in a font size no smaller than ten-point Times Roman. To comply, pharmacies would be

forced to use more paper to accommodate the required font size. As discussed above, we believe that increasing the amount of paper provided to patients would decrease the likelihood that patients would read the written materials provided to them. Furthermore, this would directly increase pharmacy's printing costs. It would also increase the amount of paper products consumed in a time when Americans are being tasked with reducing consumption and use of paper products for environmental reasons. As such, we ask the board not to make the change that was proposed for 22 TAC §291.33 (c)(1)(B)(v)(I).

We thank the Board for considering our comments. Please do not hesitate to contact us if we can further assist you.

Sincerely,



Mary Staples
Regional Director
State Government Affairs



Michelle Cope
Manager
Legislative and Regulatory Affairs

JAN-30-2009 FRI 11:06 AM

FAX NO.

P. 02/02

DaVita RxSM

OUR VILLAGE PHARMACY

January 30, 2009

Allison Benz, R.Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701

Dear Allison,

On Behalf of Davita, Rx (License # 25049), I wish to inform you that our company supports the TSBP's proposed amendments to §291.33 concerning Operational Standards.

We agree that the proposed amendments, if passed and adopted will serve to improve the readability of prescription labels and written information provided to patients by requiring the type-size of their print font to be no smaller than 10-point Times Roman. We feel this would be particularly beneficial to our geriatric patients.

We also agree that removing the requirement to include the identification code or the initials of the dispensing pharmacist on the prescription label if the information is stored in the pharmacy's data processing system is an excellent idea. This would provide us additional space on the prescription label to more effectively print required information regarding the dispensed medication.

Respectfully,

Art Solomon (KC)

Arthur C. Solomon, R.Ph.
Chief Pharmacist & PIC

Quality

Convenience

Affordability



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January 30, 2009

VIA FACSIMILIE SUBMISSION

Allison Benz, R.Ph., M.S.,
Director of Professional Services
Texas State Board of Pharmacy
Suite 3-600
333 Guadalupe Street
Austin, TX 78701
FAX (512) 305-8082

Re: Rule Number: §291.33 Prescription Dispensing and Delivery

Dear Ms. Benz:

Medco Health Solutions, Inc. ("Medco") appreciates this opportunity to offer comments on the Texas State Board of Pharmacy proposed rule to amend its rules to clarify that prescription labels and written information provided to consumers must be printed in a type-size no smaller than 10-point Times Roman. 22 TAC §291.33 (October 27, 2008). Medco strongly supports the initiative to decrease medication errors and increase overall patient outcomes through improving the clarity of written information presented to patients and on prescription containers. While we recognize the positive intention of the proposed rule, we do not want to limit the presentation to one particular font, in this case Times Roman. A final rule which permits a pharmacy to use comparable fonts, or highlight the most critical elements of the information without being confined to one font or font size would be more acceptable to Medco and achieve the same results the board desires. In addition, to further improve patient care through consistency of labeling requirements across state lines, Medco encourages the Board to consider the upcoming NABP Task Force Committee on "Uniform Prescription Labeling" recommendations when adopting its final rule.

Specific Comments

1. Amendment to TAC §291.33(c)(1)(B)(v)(I)

Issue: The proposed amendment clarifying that **patient counseling and provision of drug information communication** written information *must be in plain language designed for the consumer and printed in a type size no smaller than ten-point Times Roman* rather than an "easily readable font size," limits the opportunities a pharmacy has to further clarify, emphasize, highlight, or bold patient counseling and drug information communication.

Recommendation: The final rule should not limit type size to Times Roman, but rather allow for the use of comparable fonts that will achieve the same purpose

Suggested Language: (I) Written information must be in plain language designed for the consumer and printed in a type size comparable to, but no smaller than, ten-point Times Roman.

2. Amendment to TAC §291.33(c)(7)(A):

Issue: The proposed amendment clarifying that the information contained on the label of the dispensing container shall be *printed in a type no smaller than ten-point Times Roman* rather than *"an easily readable font size,"* limits the opportunities a pharmacy has to highlight or bold the critical elements of the prescription label. Critical elements of the pharmacy prescription label include the patient name, drug name, drug strength, directions for use, warnings, and "by use date". The patient's ability to clearly differentiate this information is a key step in increasing positive health outcomes by reducing patient medication errors. Limiting the options a pharmacy can use to present this information diverges from the good intentions of amending the current rule.

Recommendation: The final rule should not limit type size to Times Roman, but rather allow for the use of comparable fonts, specifically for critical elements of the prescription label.

Suggested Language:

(7) Labeling.

(A) At the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed in a type size comparable to, but no smaller than, ten-point Times Roman for the critical elements of the label including the patient name, drug name, drug strength, directions for use and use by date. At least the following information must also be included on the label in an easily readable font size: *See subsections (7)(i)-(iv), (viii), (ix), and (xi) for the specifically required information.*

3. Amendment to TAC §291.33(c)(7)(B):

Issue: The proposed amendment allows for pharmacies unable to meet the requirements of §291.33(c)(7)(A) to *provide the patient written information containing the information specified in subparagraph (A) of this paragraph in a type size no smaller than ten-point Times Roman,* but limits the opportunities a pharmacy has to highlight or bold the critical elements of the prescription label in its written patient information. Critical elements of a prescription for written patient information include the patient name, drug name, drug strength, directions for use, warnings, and "by use date". The patient's ability to clearly differentiate this information is a key step in increasing positive health outcomes by reducing patient medication errors. Limiting the options a pharmacy can use to present these important elements in its patient written information diverges from the positive intentions of amending the current rule.

Recommendation: The final rule should not limit type size to Times Roman, but rather allow for the use of comparable fonts that will achieve the same purpose.

Suggested Language:

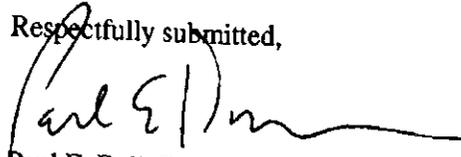
(8) Labeling.

(B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type size smaller than 10-point Times Roman, the pharmacy shall provide the patient written information containing the information specified in subparagraph (A) of this paragraph in a type size comparable to, but no smaller than, ten-point Times Roman.

Conclusion

We would be pleased to provide further information or to consult with the Texas State Board of Pharmacy regarding our views and appreciate the Board's serious consideration of these comments.

Respectfully submitted,



Paul E. DelloRusso
Assistant Counsel

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 §291.33. *Operational Standards.*

6 (a) - (b) (No change.)

7 (c) Prescription dispensing and delivery.

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

9 (A) (No change.)

10 (B) Such communication:

11 (i) - (iv) (No change.)

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

14 (I) Written information must be in plain language designed for the consumer and printed in a
15 type size **comparable to but** no smaller than ten-point Times Roman. [~~easily readable font~~
16 ~~size.~~]

17 (II) - (III) (No change.)

18 (C) - (I) (No change.)

19 (2) - (6) (No change.)

20 (7) Labeling.

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

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

25 (ii) unique identification number of the prescription **that is printed in a type size**
26 **comparable to but no smaller than ten-point Times Roman;**

27 (iii) date the prescription is dispensed;

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

29 (v) name of the prescribing practitioner;

1 (vi) name of the patient or if such drug was prescribed for an animal, the species of the
2 animal and the name of the owner **that is printed in a type size comparable to but no**
3 **smaller than ten-point Times Roman;**

4 (vii) instructions for use **that is printed in a type size comparable to but no smaller**
5 **than ten-point Times Roman;**

6 (viii) quantity dispensed;

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

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

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

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

20 (xiii) the name and strength of the actual drug product dispensed **that is printed in a**
21 **type size comparable to but no smaller than ten-point Times Roman**, unless otherwise
22 directed by the prescribing practitioner.

23 (I) The name shall be either:

24 (-a-) the brand name; or

25 (-b-) if no brand name, then the generic name and name of the manufacturer or
26 distributor of such generic drug. (The name of the manufacturer or distributor may be
27 reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to
28 identify the manufacturer or distributor. For combination drug products or non-sterile
29 compounded drug products having no brand name, the principal active ingredients shall be
30 indicated on the label.)

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

34 (B) If the prescription label required in subparagraph (A) of this paragraph is printed in a
35 type size smaller than 10-point Times Roman, the pharmacy shall provide the patient written
36 information containing the information specified in subparagraph (A) of this paragraph in a
37 type size comparable to but no smaller than ten-point Times Roman.

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

5 (D) [~~(B)~~] The dispensing container is not required to bear the label specified in subparagraph
6 (A) of this paragraph if:

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

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

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

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

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

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

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

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

18 (I) identifies the:

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

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

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

22 (-d-) name of the patient;

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

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

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

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