



July 23, 2007

Via facsimile transmission (512) 305-8082

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

Re: Comments on Proposed Rules Dated May 8, 2007 and Published in the  
June 15, 2007 Edition of the Texas Register

Dear Ms. Benz:

Please allow this correspondence to serve as American Pharmacies' formal written comments in regard to the above referenced proposed rules.

As you know, I am Vice President of Pharmacy Affairs for American Pharmacies, which was founded in 1999 by a group of independent community pharmacies who joined together so that their businesses could survive in an increasingly competitive market. American Pharmacies is a member-owned cooperative of independent community pharmacy owners who are trying to protect and grow their businesses. We remain a 100% member-owned pharmacy-buying group run by independent pharmacists, for independent pharmacists. Our combined strength gives us a strong voice in shaping legislation, which impacts our businesses and allows us to better serve our customers, Texas patients. American Pharmacies is comprised of over 500 members.

I am writing to voice American Pharmacies' Board of Directors' and members' opposition and comments in regard to a portion of the Texas State Board of Pharmacy's proposed rules dated May 8, 2007 and published in the June 15, 2007 edition of the Texas Register, which propose amendments to Title 22. Specifically, we oppose the following three (3) proposed rules:

**First Proposed Rule Opposed by American Pharmacies:**

*22 TAC § 291.33(b)(2)(B)(iii). Pharmacies. Community Pharmacy (Class A). Operational Standards. Environment. Security. Any area of a pharmacy that contains prescription drugs shall be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site except as provided in subparagraphs (C) and (D) of this paragraph and paragraph (3) of this subsection. The following is applicable: Effective, September 1, 2008, at a minimum, the pharmacy must have a basic alarm system and an electronic monitoring system to track individuals entering the area of a pharmacy that contains prescription drugs.*

American Pharmacies opposes this proposed rule on the basis that the requirement of an “electronic monitoring system” represents an extremely burdensome and expensive obligation on community pharmacies (Class A). As the Texas State Board of Pharmacy knows, community pharmacies have suffered economically due to the oppressive implementation of Medicare Part D and the effect of the Medicaid average manufacturers price (“AMP”). This new requirement proposed by the Texas State Board of Pharmacy will dramatically affect the community pharmacies’ ability to stay in business, particularly those who are currently operating on razor-thin margins. This requirement poses an unworkable financial hardship on numerous community pharmacies in order to obtain compliance. For these reasons, American Pharmacies respectfully requests that the requirement of an electronic monitoring system be deleted from Section (iii) of the above referenced proposed rule.

**Second Proposed Rule Opposed by American Pharmacies:**

*22 TAC § 291.33(b)(3)(A)(i)(III). Pharmacies. Community Pharmacy (Class A). Environment. Temporary absence of pharmacist. On-Site supervision by pharmacist. If a pharmacy is staffed by only one pharmacist, the pharmacist may leave the prescription department for breaks and meal periods without closing the prescription department and removing pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department provided the following conditions are met: the absence does not exceed 30 minutes at a time and a total of one hour in a 12 hour period.*

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July 23, 2007  
Page 3 of 5

American Pharmacies opposes this proposed rule on the basis that Section (III) of the above referenced proposed rule, pertaining to time limits for the temporary absence of a pharmacist (30 minutes at a time and a total of one hour in a 12 hour period) in regard to on-site supervision, severely undermines the professional discretion and judgment of a community pharmacist. As you know, Texas community pharmacists are trustworthy professionals already operating diligently under guidelines from a myriad of federal and state agencies, including the Texas State Board of Pharmacy, the Drug Enforcement Agency, the Texas Department of Transportation, the Food and Drug Administration, and countless more. These agencies hold community pharmacists accountable for any misconduct, wrongdoing or violations. Additionally, pharmacists are bound by their own strict professional code of ethics. In fact, the rules proposed by the Texas State Board of Pharmacy do take into account a community pharmacist's demonstrated capability to exercise sound professional judgment on a daily basis. Section (IV) of the proposed rule (the paragraph immediately following the above referenced proposed rule) states that a condition for the absence is that "the pharmacist reasonably believes that the security of the prescription department will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the prescription department should close during his or her absence, then the pharmacist shall close the prescription department and remove the pharmacy technicians, pharmacy technician trainees, or other pharmacy personnel from the prescription department during his or her absence." Due to the fact that a pharmacist's professional judgment is already a condition recognized in the proposed rules, the promulgation of time limits for the temporary absence of a pharmacist in regard to on-site supervision is unnecessary and overreaching. For these reasons, American Pharmacies respectfully requests that the portion of the proposed rule delete Section (III) of the above referenced proposed rule, which places specific time limits on the absence (30 minutes at a time and a total of one hour in a 12 hour period).

**Third Rule Opposed by American Pharmacies:**

*22 TAC § 291.33 (b)(3)(B)(i)(II). Pharmacies. Community Pharmacy (Class A). Environment. Temporary absence of pharmacist. Pharmacist is off-site. In a prescription department staffed by only one pharmacist during a shift, an agent of the pharmacist may deliver a previously verified prescription to a patient or a patient's agent during short periods of time when a pharmacist is off-site, provided the following conditions are met: short periods of time may not exceed two consecutive hours in a 24 hour period and on no more than two occasions in a calendar month.*

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July 23, 2007  
Page 4 of 5

American Pharmacies opposes this proposed rule on the basis that Section (II) of the above referenced proposed rule, pertaining to time limits for the temporary absence of a pharmacist (may not exceed two consecutive hours in a 24 hour period and on no more than two occasions in a calendar month) in regard to a pharmacist being off-site, is completely unworkable for community pharmacists. If enacted, the proposed rule would present a tremendously detrimental effect. The community pharmacists operating and owning the community pharmacies have reported to us that their financial, time and personnel resources will be severely diminished by the unfair and unnecessary time constraints contained in the proposed rules. Many community pharmacists are subject to professional obligations which require greater than two consecutive hours in a 24 hour period and more than two occasions in a calendar month, such as continuing education requirements, court-ordered appearances to provide testimony, in service meetings, meetings with physicians, advising local nursing homes and other requirements. Additionally, community pharmacists are extremely trustworthy professionals who serve critical leadership roles in assisting their communities, which demand their time away from the pharmacy periodically, such as serving on city councils, school board districts, hospital districts, mentoring youth, and many other obligations which enhance the quality of Texas communities. A responsible, competent and trustworthy pharmacist will not abuse his time away from the pharmacy (or he will hire additional pharmacist relief or full-time assistance if necessary), as any abuse would cause him to lose patients when he or she is unable to process new prescriptions for patients. American Pharmacies' Board of Directors and members are disappointed that this proposed rule would hinder pharmacists' ability to fulfill their professional obligations as well as leadership roles in their communities, which are often rural areas. Community pharmacists ask that the Texas State Board of Pharmacy take into consideration their professionalism and refrain from regulating their time off-site, much as physicians are not regulated by the Texas Medical Board when they are off-site. For these reasons, American Pharmacies respectfully requests that the portion of the proposed rule delete Section (II) of the above referenced proposed rule, which places specific time limits on the temporary absence of a pharmacist (may not exceed two consecutive hours in a 24 hour period and on no more than two occasions in a calendar month) in regard to a pharmacist being off-site.

American Pharmacies' Board of Directors' and members' greatly appreciate your and the Texas State Board of Pharmacy's thorough consideration of these written comments, and the impact that the proposed rules will have on community pharmacies in Texas. Please do not hesitate to contact me with any questions or comments.

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Texas State Board of Pharmacy  
July 23, 2007  
Page 5 of 5

Sincerely,

/s/ Richard Beck, R.Ph.  
Vice President, Pharmacy Affairs  
American Pharmacies  
11322 Sir Winston, Ste. B  
San Antonio, Texas 78216  
877-634-5445 toll free  
[rbeck@aprx.org](mailto:rbeck@aprx.org)

bcc:

Mr. Mike Gohlke, President, American Pharmacies  
Board of Directors, American Pharmacies