



Ensuring patient access to quality pharmacy care services, the viability of community pharmacy and the pharmacy profession.

April 28, 2010

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

Via facsimile transmission: (512) 305-8008

Via email [Allison.Benz@tsbp.state.tx.us](mailto:Allison.Benz@tsbp.state.tx.us)

Re: Texas Pharmacy Business Council's Formal Written Comments on Proposed Amendments as Published in the March 26, 2010 Edition of the Texas Register

Dear Ms. Benz:

My name is Richard E. Beck, R.Ph. and I am the Executive Director of the Texas Pharmacy Business Council (hereafter "TPBC"), which is a collaborative organization between American Pharmacies and the Texas Pharmacy Association's Academy of Independent Pharmacists. TPBC represents independent pharmacists and small business owners dedicated to preserving the independent pharmacy profession. Our mission is ensuring access to quality pharmacy services, the viability of community pharmacy and the pharmacy profession.

**TPBC submits to you its formal written comments and concerns with the Texas State Board of Pharmacy's (hereafter "TSBP") proposed amendments (affecting all classes of pharmacies) to new §291.7, concerning Prescription Drug Recalls by the Manufacturer.** New rule §291.7, if adopted, provides the requirements for pharmacies to follow in the event of a prescription drug recall by the manufacturer. This new rule states that in regard to prescription drug recalls by the manufacturer, the pharmacist-in-charge (hereafter "PIC") shall develop and implement a written procedure for proper management of drug recalls, and such procedures shall include contacting patients to whom recalled drug products have been dispensed, and the PIC shall ensure that a recalled drug has been removed from inventory no more than twenty-four (24) hours after his or her receipt of the drug recall

notice, and quarantined until proper disposal or destruction of the drug. The proposed rule fails to define or elaborate upon the meaning of the term "receipt," and provides no information for the PIC to ascertain proper receipt of the drug recall notice from the manufacturer. There is no reference to the appropriate procedure, rules or regulations for the manufacturer to abide by regarding the means and method of sending proper notification of a drug recall notice to the PIC. Should the manufacturer send the drug recall notice by certified mail, return receipt requested, by facsimile transmission or by electronic means? Should the manufacturer abide by the drug recall notice requirements articulated by the Food and Drug Administration (hereafter "FDA")? When is the PIC deemed to receive the drug recall notice, thereby triggering his or her twenty-four (24) hour timeline to remove the recalled drug from inventory and quarantine the drug? What are TSBP's expectations in this regard and how will it determine when a PIC received receipt of the drug recall notice? Finally, there is no indication in the proposed rule as to what level of recall the proposed amendment will govern. For instance, pharmacies are typically required to review records and contact patients only for Class I recalls, the most serious of the three (3) classes in the FDA reporting system; do these proposed amendments speak to Class I recalls, or all classes of recalls? It is unclear to TPBC what the true problem that TSBP is trying to address with these proposed amendments. Is there an issue with pharmacists not appropriately resolving drug recalls? Pharmacists are currently already regulated by the FDA in regard to this matter, and further regulation by TSBP appears superfluous and duplicative.

**TPBC also submits to you its formal written comments and concerns with TSBP proposed amendments (affecting all classes of pharmacies) to new §291.29, concerning Professional Responsibility of Pharmacist.** New rule §291.29, if adopted, clarifies the requirements for a pharmacist's corresponding responsibility in verifying the validity of prescriptions issued via the internet or without a valid patient-practitioner relationship. The entirety of these proposed amendments appear to target internet pharmacies and those Community Class A pharmacies that are filling prescriptions issued via the internet and without a valid patient-practitioner relationship. These rules undermine the professional discretion and judgment of the majority of pharmacists in good standing that do not engage in filling internet prescriptions or those issued without a valid patient-practitioner relationship. These rules place an unreasonable burden on pharmacists that do not engage in the targeted practice to "ensure that any prescription drug order has been issued for a legitimate medical purpose by a practitioner." Pharmacists do attempt to engage in this assurance with each and every prescription drug order, every day, but TPBC questions how TSBP envisions that pharmacists ensure compliance with this overly broad imposition on a day-to-day-basis. How will TSBP enforce this rule? What will TSBP expect a pharmacist to do to comply with the provision? How much energy should a PIC focus on each seemingly appropriate prescription (that is not internet based) to meet the requirement

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of TSBP that they were issued for a legitimate medical purpose and with a valid patient-practitioner relationship? The language is vague and does not appear to clearly define the terms a "legitimate medical purpose" or a "valid patient-practitioner relationship" or what is entailed to achieve these criteria. These rules are clearly an effort by TSBP to address the significant recent increase in internet pharmacies (and likely related complaints related to same). TPBC agrees with TSBP that further regulation and oversight of internet pharmacies are necessary, but it is unclear to TPBC why these new burdens are affecting all pharmacies or why the rules are written in such a way as to make compliance such a time-consuming challenge for each prescription (even if not internet based) that is filled. TPBC suggests that TSBP consider drafting an entirely separate section of rules targeting the true problem, pertaining to prescriptions issued via the internet, instead of adding these vague and unduly burdensome requirements in the "professional responsibility" standards governing all classes of pharmacists.

**TPBC also submits to you its formal written comments and concerns with TSBP's proposed amendments (affecting Community Class A Pharmacies) to §291.32, concerning Personnel.** The proposed amendments to §291.32, if adopted, provide requirements for pharmacists providing cognitive services and electronic verification of prescriptions from remote sites. These rules add language that states, "each pharmacist shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision." These rules are clearly an effort by TSBP to address the significant recent increase in mail order pharmacies (and likely related complaints related to same). TPBC agrees with TSBP that further regulation and oversight of mail order is certainly necessary, particularly to address patient safety concerns, but the proposed language is overly broad as this new standard governing delegated acts will apply to all Class A pharmacies, whether involved in mail order practice or not. Does the language holding the pharmacist responsible for a delegated act include if the pharmacy technician or pharmacy technician trainee acts grossly negligent in carrying out the delegated act? The proposed language appears rather sweeping and does not contemplate the scenario where the pharmacy technician or pharmacy technician trainee act entirely outside the scope of the instructions related to the delegated act.

**For these reasons, TPBC requests that the aforementioned rules be withdrawn entirely or re-written to address these concerns.**

**Finally, TPBC also submits to you its formal written comments as to TSBP's proposed amendments (affecting Community Class A Pharmacies) to §291.33, concerning Operational Standards.** The proposed amendments to §291.33, if adopted, implement provisions of H.B. 19 passed during the 81st Regular Session of the Texas Legislature requiring pharmacists to place the statement "Do not flush unused medications or pour down a sink or drain" on the prescription label. TPBC

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supports the effective date in this rule of January 1, 2011, which will permit pharmacists appropriate time to coordinate and install the technology necessary to comply with this new requirement.

Thank you for your time and attention to this correspondence. Please do not hesitate to contact me with questions and/or comments; my contact information is listed below.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Beck", with a stylized flourish at the end.

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cc: Texas Pharmacy Business Council Directors (via Email)