NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

April 27, 2010

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 Rules 22 TAC 291.29 (Professional Responsibility of Pharmacists); 22 TAC 291.32 (Personnel)

Dear Ms. Benz:

On behalf of the approximately 2,561 chain pharmacies operating in the state of Texas, the National Association of Chain Drug Stores ("NACDS") appreciates the opportunity to submit comments to the Texas State Board of Pharmacy ("TSBP") on the proposed new rule 22 TAC 291.29 which establishes the professional responsibility of pharmacists when filling a prescription and on the proposed revisions to 22 TAC 291.32 which would revise requirements for supervision of certain activities performed by pharmacy technicians and pharmacy technician trainees.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

22 TAC 291.29

Under 22 TAC 291.29, subsections (b), (c) and (d) require pharmacists to make "every reasonable effort" when filling a prescription to ensure that the prescription has been issued for a legitimate medical purpose by an authorized prescriber in accordance with rules of the Texas Medical Board. The proposed rules hold pharmacists directly responsible for determining whether or not a valid patient-practitioner relationship exists and/or the prescription issued was in violation of the practitioners' standard of practice. If a pharmacist knows or should have known that a prescription was issued in violation of these standards, then he or she may not dispense the prescribed drug to the patient. In adding this language, TSBP is presumably looking to establish that pharmacists may not knowingly fill prescriptions that were issued to patients on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation. Chain pharmacy supports this policy. However, we have concerns with TSBP's approach for accomplishing this aim.

First, the proposed regulation is vague with respect to what standard pharmacists must meet to demonstrate that one has made "every reasonable effort" to ensure that a prescription was issued only where a valid preexisting patient-prescriber relationship exists. This requirement is subject to interpretation. Some might argue that the only way a pharmacist could be sure that the prescription was issued for a legitimate medical purpose would be if it was issued via a hard copy prescription physically handed to the patient by the prescriber and that if a pharmacist received a prescription in any other format (oral, faxed, or electronically transmitted), the pharmacist would be obligated to call the prescriber for verbal confirmation that a valid patient-prescriber relationship exists. Clearly, this would be

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

an impractical and time consuming process. Further, if strictly interpreted, the regulation could discourage use of technology such as e-prescribing that facilitates healthcare efficiencies and benefits patients. While we do not believe that TSBP intends to impose such a requirement, we do think this language is problematic for these reasons.

Second, we are concerned that the proposed rule would require pharmacists to police the prescribing activities of prescribers to ensure that they are practicing within the confines of the laws and regulations of the Texas Medical Board, when this would more appropriately be the role of the Medical Board and its employees. Further, it could require pharmacists to second-guess the medical judgment of a prescriber, which could inappropriately delay treatment to patients.

We urge TSBP to adopt the approach taken by the Oregon Board of Pharmacy with respect to establishing pharmacists' responsibility in filling prescriptions that have been issued for a legitimate medical purpose:

> *OAR 855-019-0210.*
> Duties of the Pharmacist Receiving a Prescription.
> …
> (2) A pharmacist receiving a prescription is responsible for:
>> (a) Using professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist, in their professional judgment, believes that the prescription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner shall include a clinical associate of the practitioner or any other practitioner acting in the practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and not result solely from a questionnaire or an internet-based relationship; and

The Oregon approach places appropriate emphasis on the necessity for pharmacists to exercise professional judgment in determining whether or not a prescription was issued for a legitimate medical purpose. Pharmacists are highly trained professionals who are able to recognize when a prescription may have been issued under questionable circumstances. Accordingly, NACDS asks TSBP to revise the proposed rule by deleting the new language under 22 TAC 291.29 entirely, and to instead incorporate into the regulation the language from *OAR 855-019-0210*.

<u>22 TAC 291.32</u>

Under 22 TAC 291.32 (c)(1)(D)(iii), TSBP has proposed to establish the circumstances under which pharmacists may electronically verify the data entry of prescription information entered into a data processing system by pharmacy technicians and pharmacy technician trainees. Among other things, the proposed rule specifies that pharmacists performing electronic verification must be Texas-licensed pharmacists located onsite in the pharmacy where pharmacy technicians and pharmacy technician trainees are entering information into the data processing system. We believe that this limitation contradicts existing rules that

permit pharmacists engaged in central processing to engage in activities pertaining to data entry from off-site locations.

Specifically, 22 TAC 291.123 permits one pharmacy to process a prescription drug or medication order on behalf of another pharmacy. This process is defined to include prescription drug or medication order data entry by one pharmacy on behalf of another. The regulation, which applies to Class A, Class C & Class E pharmacies, does not require pharmacists performing data entry or other central processing functions in such pharmacies to hold a Texas pharmacist license. Thus, under the current central processing rules, a pharmacist, regardless of whether the pharmacist is licensed in Texas or in another state, may engage in activities pertaining to data entry in a central processing scenario, which we interpret to be inclusive of electronic verification of data entry of pharmacy technicians.

Additionally, under 22 TAC 291.123 (a)(2), the rule explicitly states that the central processing rules do not "…prohibit an individual pharmacist employee who is licensed in Texas from remotely accessing the pharmacy's electronic data base from outside the pharmacy in order to process prescription or medication drug orders…" Notably, under 22 §291.104(a)(12), the rules for Class E pharmacies indicate that a "…Class E pharmacy engaged in central processing of prescription drug or medication orders shall comply with the provisions of §291.123…" As such, a Class E pharmacy and the Class E pharmacists which it employs (who under 22 TAC §291.102(12) would be required only to hold a license in the state where the Class E pharmacy is located) would be subject to the same standards for central processing pharmacies that are applied to other pharmacies, including the provision that permits pharmacists off-site to remotely access pharmacy's data base to process a prescription order. Thus, under the current central processing rules and Class E pharmacy rules, a pharmacist, regardless of whether the pharmacist is licensed in Texas or in another state, working at an off-site location may engage in activities pertaining to data entry in a central processing scenario, which as previously stated, we interpret to be inclusive of electronic verification of data entry of pharmacy technicians.

Since technology exists that permits pharmacists at off-site locations to accurately verify the data entry of pharmacy technicians and pharmacy trainees, we ask TSBP to resolve this apparent inconsistency between the proposed revision to 22 TAC 291.32 (c)(1)(D)(iii) and the existing rules by revising the proposed rule as follows:

(c)(1)(D) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees who are entering prescription data into the pharmacy's data processing system by one of the following methods.

(iii) Electronic verification of data entry by pharmacy technicians or pharmacy technician trainees. A pharmacist may electronically verify the data entry of prescription information into a data processing system provided:

(I) ~~**a pharmacist is onsite in the pharmacy where the pharmacy technicians/trainees are located;**~~

~~**(II) the pharmacist electronically conducting the verification is a Texas licensed pharmacist;**~~

(~~III~~) the pharmacy establishes controls to protect the privacy and security of confidential records; and
(~~IV~~ ***II***) the pharmacy keeps permanent records of prescriptions electronically verified for a period of two years.

NACDS thanks TSBP for considering our comments on these matters. Please do not hesitate to contact me with any questions or for further assistance. I can be reached at: 817-442-1155 or mstaples@nacds.org.

Sincerely,

Mary Staples
Regional Director, State Government Affairs