

January 20, 2016

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

Via email: allison.benz@pharmacy.texas.gov

Re: Proposed Rules under 22 TAC §§315.1 - 315.14

Dear Ms. Benz:

On behalf of our members operating approximately 2,821 chain pharmacies in the state of Texas, the National Association of Chain Drug Stores (NACDS) thanks the Texas State Board of Pharmacy (TSBP) for the opportunity to comment on the proposed rulemaking under 22 TAC §§315.1 - 315.14 implementing SB 195 (2015) and transferring the Prescription Monitoring Program from the Texas Department of Public Safety to the Texas State Board of Pharmacy. We appreciate TSBP considering our views on this matter.

As chain pharmacy has long promoted moving the Prescription Monitoring Program under the purview of TSBP, we support this rulemaking formalizing this change. Related to TSBP's new oversight authority for the Prescription Monitoring program, there are several issues that TSBP should be mindful of during this period of transition. First, we encourage TSBP to maintain the existing reporting format should a new vendor be selected to manage the program. Doing so will promote a more seamless transition for pharmacies and other dispensers who report into the program. Second, if the Board opts to pursue any program changes that impact the format, data content or timelines for reporting controlled substances prescriptions in the future, we request that TSBP allow at least 180 days before implementing any changes so that pharmacies can perform any necessary system changes.

In addition to these matters, we have also identified various provisions in the proposed rules that warrant further clarification. These include the following:

- 315.5 (a)(3) & (5): These provisions appear to reference practices that would be satisfied by general recordkeeping performed within the standard processing of a prescription. To clarify this, we ask that 315.5 (a)(3) & (5) be revised as follows:

(a) Upon receipt of a properly completed prescription form, a dispensing pharmacist must:

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...

(3) **enter record** the date dispensed and the pharmacy prescription number;

...

(5) if issued on an official prescription form, **enter record** the following information, if different from the prescribing practitioner's information:

(A) the brand name or, if none, the generic name of the controlled substance dispensed; or

(B) the strength, quantity, and dosage form of the Schedule II controlled substance used to prepare the mixture or compound.

- 315.6: We ask TSBP to further amend the rules to clearly specify that pharmacies must report dispensed controlled substances information within seven days (which is what is currently required of pharmacies under the existing program and under the Texas Health & Safety Code § 481.075 (i)(3)) by revising the first paragraph of 315.6 as follows:

Within **the time required by the TCSA seven days after the date a controlled substance prescription is dispensed**, a pharmacy must electronically submit to the board the following data elements from all dispensed controlled substance prescriptions:

- 315.6 (2): The proposed rule maintains the existing requirement for pharmacies to report the official prescription form control number for controlled substances prescriptions. Notably, the overwhelming majority of states that operate prescription monitoring programs (47 states in total) do not require this value to be reported, including several states that employ a serialized prescription form program similar to the Texas Official Prescription Program. Given that this unique requirement impedes the more timely uploading of prescription data, we ask TSBP to eliminate the requirement for pharmacies to report the official prescription form control number by deleting the language under 315.6 (2):

(2) the official prescription form control number if dispensed from a written official prescription form, unless the prescription is electronic and meets the requirements of Code of Federal Regulations, Title 21, Part 1311;

Finally, we encourage TSBP to address an issue related to pharmacist access to prescription information from the Prescription Monitoring Program. While the existing laws and rules facilitate access to program data for pharmacists linked to a specific retail pharmacy setting, accessing program data remains challenging for

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pharmacists whose licenses are not tied to a particular pharmacy registrant. Recognizing the role that prescription monitoring programs have in preventing drug abuse and diversion, this important public health goal would be better served by eliminating unnecessary barriers that impede access to program data for floater pharmacists and other pharmacists who work in unique settings. Accordingly, we ask TSBP to pursue any statutory and/or regulatory changes necessary to allow Texas pharmacists whose licenses are not tied to a particular pharmacy registrant to access to Prescription Monitoring Program information.

NACDS thanks TSBP for considering our comments on this matter. 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,

A handwritten signature in black ink that reads "Mary Staples". The signature is written in a cursive, flowing style.

Mary Staples

cc: Brad Shields II, TFDS