

TEXAS STATE BOARD OF PHARMACY GUIDELINES FOR DISPENSING ERROR COMPLAINTS

The mission of the Texas State Board of Pharmacy (TSBP) is to promote and protect the public health, safety and welfare, and specifically, consumers of pharmacy services in Texas. If numerous dispensing errors are occurring in a pharmacy or are being committed by an individual pharmacist, it is TSBP's duty and responsibility to take corrective action.

To handle complaints alleging that a dispensing error has occurred, TSBP has established the following guidelines.

- # After the receipt of the first dispensing error complaint and applicable evidence, TSBP sends a warning letter, by certified mail, to the pharmacist who allegedly made the error and to the pharmacy where the alleged error occurred.
- # After the receipt of the second dispensing error complaint and applicable evidence, TSBP mails a second warning letter, by certified mail, to the pharmacist who allegedly made the error and to the pharmacy where the alleged error occurred.
- # If a third dispensing error complaint is filed against a pharmacist and/or pharmacy within approximately 2 years after the date of the receipt of the first dispensing error complaint, TSBP would investigate the complaint and institute disciplinary action against the pharmacist who allegedly made the error and the pharmacy where the alleged error occurred, if the allegations were confirmed upon investigation.

Generally, TSBP institutes disciplinary action only after the agency has received three complaints within a two-year period of time. However, there are **exceptions** to these guidelines, including:

- (1) complaints alleging ***multiple errors*** within a two-year period of time, in which case, the first or second complaint may be closed with a warning letter or may result in disciplinary action being instituted against the licensees involved, if the allegations were confirmed upon investigation;
- (2) complaints filed against a licensee with ***extensive complaint history*** (e.g., multiple complaints alleging different types of violations), in which case, the first or second complaint may be closed with a warning letter or may result in disciplinary action being instituted against the licensees involved, if the allegations were confirmed upon investigation;
- (3) complaints alleging that the dispensing error posed a ***risk to the public health, safety, and welfare*** (e.g., errors resulting or possibly resulting in excessive dosage of medication to the patient; errors resulting in adverse drug reactions; and factors such as the nature and toxicity of the drug and the age and condition of the patient), in which case, the first complaint may be investigated and result in disciplinary action being instituted against the

licensees involved, if the allegations were confirmed upon investigation;

- (4) complaints alleging that a dispensing error **resulted in harm** to the patient (as substantiated by a practitioner's statement or medical records when the alleged error resulted in a hospitalization, emergency room visit, or treatment by a physician), in which case, the first complaint may be investigated and result in disciplinary action being instituted against the licensees involved, if the allegations were confirmed upon investigation; and
- (5) complaints alleging that a dispensing error **caused serious injury or death**, in which case the first complaint would be investigated and result in disciplinary action being instituted against the licensees involved, if the allegations were confirmed upon investigation.

In most cases, however, after receipt of the first warning letter, the licensee takes corrective action resulting in no further complaints to TSBP.

The disciplinary sanction most often imposed in cases involving a dispensing error is a "public reprimand," which is the least severe sanction that TSBP may impose on a licensee. However, the disciplinary sanction may be more severe if there are aggravating factors (e.g., patient harm; the severity of the harm; the seriousness of the error; prior disciplinary action; and the number of alleged violations that have occurred). In addition, TSBP may consider extenuating and mitigating factors (e.g., implementation of remedial measures). More recently, disciplinary orders have imposed some type of "outcome based regulation" requiring the licensee(s) to develop and implement quality assurance systems to detect errors, to rectify errors that have occurred, and to prevent future errors. TSBP believes that this type of sanction offers the potential for reducing the number of prescription errors.

TSBP believes that its policy regarding the regulation and discipline of licensees is a reasonable and prudent approach, given the fact that dispensing error complaints involve quality assurance issues that have a direct impact on public health.