

HISTORY OF THE TEXAS STATE BOARD OF PHARMACY'S PATIENT COUNSELING REGULATIONS

- Fall 1986 The Texas State Board of Pharmacy (TSBP) established a Joint Advisory Committee on Class A and Class C Pharmacies. This Advisory Committee was appointed to review crucial issues relating to the standards of practice in Class A and Class C pharmacies.
- July 1987 The Joint Advisory Committee presented its recommendations to the Board. Included in the recommendations was one that would expand the duties of pharmacists to include a requirement that pharmacist provide patient counseling. To allow pharmacists time to counsel their patients, the Joint Advisory Committee recommended that pharmacy technician duties also be expanded to include counting, pouring, and labeling a prescription under the supervision of a pharmacist.
- September 1987 TSBP formed an a "Liaison Committee" composed of representatives of the Texas Pharmacy Association, Texas Society of Hospital Pharmacists, Texas Federation of Drug Stores, and the National Pharmaceutical Association to obtain input from the profession regarding the recommendations of the Joint Advisory Committee.
- February 23, 1988 The "Liaison Committee" presented its recommendations to the Board with one modification that would require pharmacist to counsel patients if the pharmacist deemed counseling was necessary thus establishing a "voluntary" rather than "mandatory" requirement for counseling. After receiving the report, the Board voted to propose rules that included the "Liaison Committee's" suggestions and included language that would allow pharmacy technicians to perform additional duties including counting, pouring, and labeling a prescription under the supervision of a pharmacist.
- April 26, 1988 TSBP held a public hearing on the proposed rules. After the hearing, the Board extended the comment period through May 1988 in order to receive more input.
- August 3-5, 1988 The Board voted to adopt the proposed rules that:
1. required pharmacies to have an area that is suitable for confidential patient counseling;
 2. specified that pharmacists must provide patient counseling when the patient requested information and if the pharmacist determined counseling was necessary (voluntary);
 3. allowed pharmacy technicians to perform expanded duties including counting, pouring, and labeling a prescription under the supervision of a pharmacist.
- September 12, 1988 The Texas Pharmacy Association (TPA) filed for and was granted a temporary restraining order that prohibited the rules regarding the expanded duties of pharmacy technicians from becoming effective. **The provisions of the rules that dealt with patient counseling were not included in the restraining order and these rules became effective on September 14, 1988.**
- July 17, 1989 TPA and TSBP reached an agreement to settle the lawsuit filed on September 12, 1988. This agreement allowed pharmacy technicians to count and pour but pharmacy technicians would not be able to label prescriptions.
- November 5, 1990 The Federal Omnibus Budget Reconciliation Act of 1990 (OBRA '90) was signed into law on November 5, 1990. This Act amended the 1965 Medicaid law to condition Federal Medicaid payments for outpatient drugs on:
1. the participation of drug manufacturers in state rebate programs;
 2. the development of drug use review programs; and
 3. and implementation of patient counseling requirements by the states.
- OBRA '90 requires a pharmacist to:
1. to "offer" the patient "counseling" about their prescription; and
 2. conduct a drug use review that at a minimum identifies clinically significant:
 - inappropriate drug utilization;
 - therapeutic duplication;
 - drug-disease contraindications;

- drug-drug interactions;
- incorrect drug dosage or duration of drug treatment;
- drug-allergy interactions; and
- clinical abuse/misuse.

August 5, 1992 The Board votes to propose rules that will implement the provisions of the OBRA '90 and set standards for patient counseling and prospective drug review for all patients by pharmacists in Class A pharmacies in Texas.

January 1, 1993 The August proposed rules to implement the requirements of OBRA '90 become effective. These rules require pharmacists to conduct prospective drug use review and require pharmacists to counsel patients on all new prescriptions. (Note these rules differed from the OBRA '90 requirements in that the rules **required** pharmacists to counsel patients where OBRA '90 only required pharmacists to "offer" counseling to the patient. This is the first time the rules make patient counseling **mandatory** on new prescriptions.

December 21, 1993 TSBP rules became effective that gave more description of the counseling area. These rules specified that the counseling area must be:

1. easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;
2. designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

The rules also specified that in determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following.

1. the proximity of the counseling area to the check-out or cash register area;
2. the volume of pedestrian traffic in and around the counseling area;
3. the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and
4. any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

February 2004 TSBP appoints a "Task Force on Patient Counseling" to review current rules, policies, and administrative penalties concerning counseling.

November 9, 2004 The final report of the "Task Force on Patient Counseling" is presented to the Board. The Board directs staff to draft language that will incorporate the suggestions made by the Board during discussion of the task force recommendations, including a requirement that pharmacists must counsel on all new prescriptions (which is currently required under TSBP rules) and adding a requirement that pharmacists must offer to counsel on refill prescriptions.

June 12, 2005 Rules become effective that implement a portion of the recommendations of the Task Force on Patient Counseling. The rules:

1. require a pharmacist to ensure that the patient or patient's agent is offered information about refill prescriptions; and
2. require pharmacies to post notification in the pharmacy that a pharmacist is available to answer questions about prescription medications.