



TEXAS HEALTH AND HUMAN SERVICES COMMISSION
Texas Medicaid/CHIP Vendor Drug Program

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**Texas State Board of Pharmacy
Prospective Drug Use Review and Patient Counseling Rules**

1. Why has the Board adopted rules for prospective drug use review (DUR) and patient counseling?

Congress enacted the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) requiring pharmacists to conduct prospective drug use reviews and to provide patient counseling for all Medicaid patients. Rather than allow two different levels of pharmacy service (one level for Medicaid patients and another level for everyone else), the Board's Rules extend the requirements to **ALL** patients.

In developing these rules, the Texas State Board of Pharmacy worked closely with the Texas Department of Human Services, the agency responsible under OBRA '90 for implementation of these requirements for Medicaid patients. Consequently, a pharmacy which is in compliance with these new rules will also be in compliance with the prospective drug use review and patient counseling requirements for Medicaid patients.

2. What is the purpose of these new rules?

The Texas State Board of Pharmacy strongly endorses the concept of "*Pharmaceutical Care*." This is a concept whereby pharmacists not only provide a drug product to a patient, but also the clinical services and information necessary to properly use the drug product to help assure positive patient outcomes.

Studies have shown that 30 to 50% of all prescriptions fail to produce the desired results because they are used improperly. Over 500,000 hospitalizations per year are the result of drug reactions.

Clearly, these statistics underscore the need for pharmacists to provide pharmaceutical care. Many pharmacists have been providing this level of care for some time and we applaud the efforts of those individuals. With these rules, a new practice standard for the provision of pharmaceutical care is established.

3. Do these rules apply only to Class A (Community) Pharmacies?

No. The rules apply to any pharmacy that dispenses prescription drug orders. This includes class A Pharmacies and any other class of pharmacy that dispenses prescription drug orders in accordance with Class A rules. For example, the rules would apply to a Class C (Institutional) Pharmacy that dispenses discharge orders or dispenses prescriptions to employees.

4. When do these new rules take effect?

On January 1, 1993.

5. What do the new rules involve?

The rules actually require a three-step process for pharmacists.

- a. The pharmacist must make a reasonable effort to obtain, record, and maintain a patient medication record (PMR) on each patient.
- b. The pharmacist must examine the patient's medication record and conduct a prospective drug use review when filling or refilling a prescription.
- c. Following the drug use review, the pharmacist must counsel the patient or the patient's agent about the drug dispensed.

Each of these steps will be discussed in subsequent questions.

6. What information is required in the patient medication record?

The pharmacist is responsible for seeing that the following information is obtained and placed in the patient's medication record:

- a. Full name of the patient for whom the drug is prescribed;
- b. Address and telephone number of the patient;
- c. Patient's age or date of birth;
- d. Patient's gender;
- e. Any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs currently being used by the patient which may relate to prospective drug review;
- f. Pharmacist's comments relevant to the individual's drug therapy, including any other information unique to the specific patient or drug; and
- g. A list of all prescription drug orders dispensed (new and refill) to the patient by the pharmacy during the last two years. Such list shall contain the following information:
 - i. Date dispensed;
 - ii. Name, strength, and quantity of the drug dispensed;
 - iii. Prescribing practitioner's name;
 - iv. Unique identification number of the prescription; and
 - v. Name or initials of the dispensing pharmacist.

This patient medication record (PMR) may be maintained manually or in the computer. With either method, the PMR must be maintained in the pharmacy for two years. If the PMR is maintained in a computer, the previous 12 month's of information must be maintained on-line.

7. What if the patient refuses to provide information required for the PMR?

A pharmacist is not required to obtain, record, or maintain patient information if the patient refuses to provide the information. Of course, prescription drug order information must continue to be maintained for all prescriptions dispensed by the pharmacy.

8. What is a prospective drug use renew?

A prospective drug use review (DUR) is defined as a review of a patient's medication record and prescription drug order **PRIOR to dispensing the medication**. Prior to dispensing both new and refill prescriptions, a pharmacist must conduct this review and identify clinically significant:

- a. Inappropriate drug utilization;
- b. Therapeutic duplication;
- c. Drug-disease contraindications;
- d. Drug-drug interactions;
- e. Incorrect drug dosage or duration of drug treatment;
- f. Drug-allergy interactions; and
- g. Clinical abuse/misuse.

If the pharmacist identifies a significant problem, the pharmacist must take steps to avoid or resolve the problem including consulting the prescribing practitioner.

9. Is the pharmacist required to personally conduct the prospective DUR?

Yes. Only a pharmacist may conduct the required prospective drug use review?

10. Which patients must be counseled?

All patients except inpatients of hospitals, nursing homes or other facilities where drugs are administered to patients by a person required to do so by the laws of the state.

11. Are pharmacists required to personally counsel patients?

Yes. A pharmacist must verbally counsel patients in person concerning their drug therapy unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits oral communication. In a pharmacy setting, only the pharmacist has the necessary level of knowledge and training needed to effectively counsel patients on the use of their medications.

12. Do I have to counsel on all prescriptions?

A pharmacist must counsel the patient or patient's agent on **all new** prescription drug orders. A new prescription drug order is defined as a prescription for a drug not previously taken by the patient. However, the pharmacist is allowed to use his or her professional judgement to determine if counseling is needed when dispensing a prescription refill.

Please note that the pharmacist must perform the drug use review for all prescriptions dispensed, both new and refill. Using the information obtained in the drug use review, the pharmacist can then determine if counseling is appropriate when dispensing a refill. but **must** counsel on a new prescription.

13. Can sign advising patients that "Counseling is available upon Request" satisfy the patient counseling requirement?

No. The posting of a sign does not satisfy the patient counseling requirement. A pharmacist must counsel the patient face-to-face. However, a sign which emphasizes the value of patient counseling may be a worthwhile addition to augment the patient's understanding of the requirement.

14. What must the pharmacist discuss with the patient?

Patient counseling is defined as communication by the pharmacist of information to the patient or patient's agent, in order to improve therapy by ensuring proper use of drugs and devices. Once the pharmacist has collected patient information and has reviewed the patient's medication record for problems, a vital link in the provision of pharmaceutical care can occur. The pharmacist now has the information necessary to properly counsel the patient or patient's agent in order to improve their individual drug therapy.

Content of this counseling may drastically affect the therapeutic outcome of the course of drug therapy. Therefore, the pharmacist must discuss any information about the drug or device dispensed, which in the professional judgement of the pharmacist is necessary for the proper use of the drug. Examples of the type of information which may be covered include:

- a. The name and description of the drug or device;
- b. Dosage form, dosage, route of administration, and duration of drug therapy;
- c. Special directions and precautions for preparation, administration, and use by the patient;
- d. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- e. Techniques for self monitoring of drug therapy;
- f. Proper storage;
- g. Refill information; and
- h. Action to be taken in the event of a missed dose.

15. What if a patient refuses consultation?

The pharmacist is not required to counsel if the patient or patient's agent refuses counseling. It is hoped that an effort will be made to explain to the patient or patient's agent the importance of the information to be communicated.

If the patient still refuses counseling, the pharmacist is required to document the refusal. This documentation may be maintained in the computer or manually in a manner which clearly indicates that the patient refused counseling.

16. Are pharmacies required to have a area suitable for patient consultation?

Yes, for all new Class A pharmacies. This requirement has been in effect for new pharmacies since June 1, 1989. However, under the new rules, ALL CLASS A Pharmacies must have an area suitable for confidential patient counseling by January 1, 1995. This also includes Class B and C pharmacies, when those pharmacies dispense prescription drug orders in accordance with Class A requirements.

17. Is written information required to be given to a patient who picks up their prescription at the pharmacy?

Yes, but not until September 1, 1993. On that date written information to reinforce verbal consultation must be provided to every patient at the time of dispensing. This delay is to allow ample time to establish procedures to accomplish this requirement. It is hoped that pharmacists will comply with this requirement as soon as possible, rather than waiting until September 1, 1993. For delivered prescriptions, see question number 21.

18. Can written information be given to the patient instead of face-to-face counseling by a pharmacist?

No. Written information is intended to complement direct patient counseling by reinforcing and expanding on the information provided verbally.

19. Can supportive personnel perform any of the duties required?

As previously stated, only a pharmacist may conduct the prospective drug use review and counsel the patient or patient's agent. Supportive personnel may obtain and record information required on the patient medication record. Although information gathering for the PMR may be delegated to supportive personnel, the pharmacist remains responsible for the accuracy and completeness of the information contained in the PMR.

20. Can pharmacist-interns perform any of the duties required?

Yes. Pharmacist-interns may perform all functions associated with information gathering, prospective DUR, and patient counseling while under the direct supervision of a pharmacist-preceptor registered with the Board. The pharmacist-preceptor remains responsible for ensuring that the intern's work is accurate and complete.

21. How can the requirements for patient counseling be met when prescriptions are delivered to the patient?

When prescriptions are delivered to a patient by delivery service, U.S. Mail, or other carrier, the pharmacy must provide:

- a. Written information which accompanies the prescription concerning the drug(s) dispensed;
- b. A toll-free telephone line which is answered during normal business hours and allows access to a pharmacist, if the pharmacy routinely delivers outside the area covered by the pharmacy's local telephone service; and
- c. On or with the delivered prescription in English and Spanish:
Local and if applicable, the toll free telephone number of the pharmacy; and the statement:

"Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."

22. What are the consequences for failure to comply with the new prospective DUR and patient counseling requirements?

A pharmacist or pharmacy that fails to meet these minimum requirements for prospective DUR or patient counseling could face possible disciplinary action by the Board. Furthermore, if the patient is a Medicaid recipient, the pharmacist and his or her pharmacy could be sanctioned by the Department of Human Services which could affect its ability to participate in the Medicaid Drug Vendor Program. Thus, it is important that the Board's requirements implementing prospective DUR and patient counseling requirements of OBRA '90 be fully understood.

The Board's approach to enforcement of the rules will be through education and preventive efforts for a reasonable period of time. This will give pharmacists and pharmacies time to implement certain requirements of the rules. If, however, the agency receives complaints involving non-compliance with the new rules, at any time after the January 1, 1993, effective date, it will be obligated to act. Any such action would initially be based upon the agency's education/prevention enforcement approach.

23. Who should I contact if I have other questions concerning these new rules?

If you have other questions about the Board's requirements for prospective DUR or patient counseling, you are encouraged to contact the Compliance Division of the Texas State Board of Pharmacy at 512-832-0661.

<http://www.tsbp.state.tx.us>