

CANDIDATE'S GUIDE TO THE TEXAS PHARMACY JURISPRUDENCE EXAM

As required by the Texas Pharmacy Act, the Texas State Board of Pharmacy administers a Texas Pharmacy Jurisprudence Exam to candidates for licensure in Texas.

TEXAS PHARMACY JURISPRUDENCE EXAM

- The Board uses the services of the National Association of Boards of Pharmacy (NABP), and administers their Multistate Pharmacy Jurisprudence Exam (MPJE). Although the MPJE is developed for use by multiple states, all of the exam questions on the Texas version of the exam are applicable to pharmacy practice in Texas. This exam is a comprehensive exam, which includes questions on both federal and state statutes and rules pertaining to the practice of pharmacy in Texas.
- The exam is designed to measure each applicant's knowledge of pharmacy law. Candidates should be aware of conflicting areas between Texas and Federal laws and rules and should answer exam questions on the basis of the more stringent statute or rule. You will be given 2 hours to answer 90 multiple choice questions.
- Since the exam is a qualifying exam, applicants are not competing against each other for a passing score. An applicant is required to attain a score of no less than 75 on the exam. The score is calculated by first determining the candidate's ability level on the MPJE, and then comparing the candidate's ability level to the predetermined minimum acceptable ability level established for the MPJE. An applicant who passes NAPLEX but fails the Texas Pharmacy Jurisprudence Exam is required to repeat only the Jurisprudence exam. If an applicant passes the Texas Pharmacy Jurisprudence Exam but fails NAPLEX, the applicant may use the passing grade on the Jurisprudence examination for licensure purposes for a period of two years from the date of passing the exam.

COMPETENCY OBJECTIVES

- The MPJE Competency Statements, found in the MPJE Registration Bulletin, serve as the blueprint for the topics covered on the Texas Pharmacy Jurisprudence Examination. The competency objectives contained in this document are a detailed **supplement** to the MPJE Competency Statements.
- The attached list of competency objectives provides a guide to the facts and information that you should be prepared to apply to practical situations. Although the exam is a multiple choice exam, the competency objectives are written in an essay format. Test experts believe that one of the best ways to prepare for an exam, is to prepare for an essay exam.

HOW TO OBTAIN COPIES OF LAWS AND REGULATIONS

The following Laws and Rules may be obtained for a fee by ordering the current (01/31/00) copy of the publication titled *Pharmacy Laws and Regulations* from the Texas State Board of Pharmacy.

- U Texas Pharmacy Act and Rules
- U DEA Pharmacist's Manual (summary publication of the Federal Controlled Substances Act and Rules - also includes U. S. Postal Regulations)
- U Texas Controlled Substances Act and Rules
- U Texas Food, Drug and Cosmetic Act
- U Texas Dangerous Drug Act
- U Summary of pertinent portions of the Texas Optometry Act

**Contact: Texas State Board of Pharmacy
William P. Hobby, Jr. Building, Suite 3-600
333 Guadalupe, Box 21
Austin, TX 78701-3942
(512) 305-8000**

In addition, the following Act and Rules may be separately ordered free of charge from the Texas State Board of Pharmacy.

- U Poison Prevention Packaging Act (summary publication)

Contact: Texas State Board of Pharmacy (see address above)

One copy of the Federal Food, Drug and Cosmetic Act and related laws may be obtained free of charge by ordering HHS Publication No. (FDA) 86-1051.

**Contact: U. S. Food and Drug Administration
Attn: Carlos Aranguren, H. F. I.- 40
5600 Fishers Lane
Rockville, MD 20857**

Please note that the Texas Food, Drug and Cosmetic Act is patterned after and tracks the Federal Act very closely.

**TEXAS STATE BOARD OF PHARMACY
JURISPRUDENCE EXAM COMPETENCY OBJECTIVES**

I. Texas Pharmacy Act

Objectives: The candidate should be prepared to:

1. discuss the purpose of the Board;
2. explain the definitions in the Act;
3. describe the qualifications for membership and the make-up of the Board;
4. explain the rule-making authority of the Board;
5. discuss the responsibilities of the Board;
6. discuss inspections by the Board or its representative;
7. explain unlawful practice of pharmacy;
8. discuss pharmacist-intern registration;
9. discuss the number of times a licensing exam may be retaken;
10. list qualifications for licensing by examination and by reciprocity;
11. describe requirements for display of a pharmacist's license and renewal certificate;
12. discuss renewal of a pharmacist's license;
13. describe the mandatory continuing education requirements for renewing a pharmacist license;
14. describe the procedures and effects of placing a pharmacist license on inactive status;
15. list grounds for discipline of a pharmacist's and a pharmacy's license;
16. discuss disciplinary action in a Class E Pharmacy;
17. discuss temporary suspension of a pharmacist's and a pharmacy's license;
18. discuss the penalties that may be imposed by the Board and methods for reinstatement of a license;
19. describe the application procedures for licensure and renewal of pharmacy licenses;
20. list and give time limits for the items that must be reported to the Board by a pharmacy and pharmacist;
21. discuss administration and provision of dangerous drugs by practitioners;
22. discuss the unlawful use of the word "Pharmacy" and the title "Registered Pharmacist;"
23. discuss the requirements for drug substitution;
24. discuss the requirements for emergency refills; and
25. discuss the requirements for release of confidential records.

II. Texas Pharmacy Rules of Procedure

Objectives: The candidate should be prepared to:

1. discuss the items that constitute "unprofessional conduct," "gross immorality," or "fraud, deceit or misrepresentation" in the practice of pharmacy, as grounds for discipline of a pharmacist license;
2. discuss the items that constitute failure to establish and maintain effective controls against diversion of prescription drugs as grounds for discipline of a pharmacy license;
3. describe Board disciplinary procedures against a licensee;
4. discuss the application procedure for reissuance or removal of restrictions on a license;
5. discuss the goals and objectives of internship, the requirements for the Texas Colleges' of Pharmacy internship programs, and the requirements for graduates of out-of-state colleges of pharmacy;
6. explain the extended internship program;
7. discuss the duties that a pharmacist-intern may perform;
8. describe preceptor requirements;
9. discuss examination and reciprocity requirements;
10. explain the requirements for renewal of a pharmacist's license which has expired;

11. describe procedures for change of location, name, ownership, or managing officers of a pharmacy;
12. describe the procedures for closing a pharmacy;
13. discuss the return of dispensed prescription drugs;
14. discuss the requirements for prescription pick-up locations;
15. describe the responsibilities of the pharmacist-in-charge of a pharmacy which experiences a fire or other disaster;
16. discuss notification of theft or loss of a controlled substance or dangerous drug;
17. discuss the Board's inventory requirements;
18. explain the requirements for, and the differences in, the requirements for personnel, operational standards, and records in a:
 - ! Class A (Community) Pharmacy;
 - ! Class A (Community) Pharmacies Compounding Sterile Pharmaceuticals;
 - ! Class B (Nuclear) Pharmacy;
 - ! Class C (Institutional) Pharmacy;
 - ! Class C (Institutional) Pharmacy Located in a Freestanding Ambulatory Surgical Center;
 - ! Class D (Clinic) Pharmacy; and
 - ! Class E (Non-Resident) Pharmacy;
19. explain the similarities and differences in the requirements for the use of pharmacy technicians; their duties, ratios, and training in each class of pharmacy listed in number 18;
20. discuss the responsibilities of the pharmacist-in-charge in each of the classes of pharmacy;
21. discuss the pharmacist's responsibilities for patient counseling and the provision of drug information to patients in Class A pharmacies;
22. discuss the requirements for patient medication records in Class A and Class C pharmacies;
23. discuss drug regimen review requirements in Class A and Class C pharmacies;
24. discuss identification of pharmacy personnel in Class A and Class C pharmacies;
25. describe security requirements for each of the classes of pharmacy;
26. describe the requirements for the temporary absence of a pharmacist in Class A (Community) pharmacies;
27. describe the three-file system for prescriptions that is required in Texas;
28. explain the requirements for written, verbal, and facsimile (FAX) prescriptions;
29. list the requirements for a prescription label;
30. explain the requirements for the use of automation in pharmacies;
31. discuss refill requirements for dangerous drugs and controlled substances;
32. explain the procedures for documenting refill authorization;
33. relate the procedures for telephonic and electronic transfer of prescription information between pharmacies;
34. discuss the requirements for maintaining prescription records in a data processing system;
35. discuss Schedule II controlled substance official prescription requirements and exceptions to the use of Schedule II controlled substance official prescriptions;
36. discuss the requirements and restrictions for prescriptions issued by practitioners not licensed in Texas;
37. discuss the requirements and restrictions for drug therapy management and for administration of immunizations and vaccinations, by a pharmacist under written protocol of a physician;
38. discuss the requirements and restrictions for prescriptions carried out or signed by advanced practice nurses and physician assistants;
39. discuss the requirements for a Class A Pharmacy that compounds sterile pharmaceuticals;
40. describe the requirements for inpatient records of a hospital or ambulatory surgical center;
41. discuss the absence of pharmacist records in a Class C Pharmacy;
42. discuss the requirements for clinical services in a Class A Pharmacy Compounding Sterile Pharmaceuticals and a Class C Pharmacy;
43. discuss the requirements for maintaining records in a data processing system in a Class C Pharmacy;

44. describe the requirements for supplying drugs from the emergency room or radiology department of a hospital;
45. discuss the requirements for dispensing prescriptions to outpatients of a hospital;
46. discuss record requirements for Schedule II controlled substances and floor stock in a Class C Pharmacy;
47. describe the limitations for a Class D Pharmacy drug/device formulary and the petition process for an expanded formulary;
48. explain the requirements for pharmacist supervision in a Class D Pharmacy and the petition process for an alternative visitation schedule;
49. discuss the requirements for Class E pharmacies mailing prescriptions to Texas patients;
50. discuss the regulations governing pharmacists;
51. explain the procedures for reporting approved continuing education and the penalties for reporting falsely;
52. discuss the procedures for placing a pharmacist's license on inactive status and for reactivating an inactive license;
53. list the requirements for destruction of dispensed drugs;
54. list the requirements for disposal of stock prescription drugs; and
55. discuss the regulations concerning generic substitution.

III. Federal and State Controlled Substances Acts and Regulations

Objectives: The candidate should be prepared to:

1. discuss the terms defined in the State and Federal Controlled Substances Acts (CSA);
2. discuss who must register with the Drug Enforcement Administration (DEA) and the Texas Department of Public Safety (DPS);
3. describe types of registration and procedures for registering with DEA and DPS;
4. relate the procedures and limitations to distribute controlled substances from one registrant to another without obtaining a second registration;
5. discuss the storage requirements for controlled substances in pharmacies;
6. list all records that must be maintained for acquisition of controlled substances;
7. list all records that must be maintained for dispensing and disposition of controlled substances;
8. describe central recordkeeping requirements and restrictions;
9. discuss the requirements for obtaining, executing, and storing DEA order forms;
10. describe the procedures to follow for a theft or loss of DEA order forms;
11. describe the correct procedures for the return of controlled substances to a supplier;
12. state methods for disposing of expired or contaminated controlled substances;
13. list the legal requirements of prescriptions for Schedule II, III, IV, and V controlled substances;
14. discuss the specific refill requirements for Schedule II, III, IV, and V controlled substances;
15. discuss emergency refill requirements for Schedule III, IV, and V controlled substances;
16. describe the requirements for partial dispensing of Schedule II and Schedule III, IV, and V controlled substances;
17. describe the procedure for a pharmacist accepting an emergency oral order for a Schedule II controlled substance, and the pharmacist's responsibilities;
18. describe the Federal "transfer warning" statement and the requirements for its use;
19. explain the possible implications for knowingly dispensing a forged or altered prescription;
20. discuss the Texas CSA restrictions on the sale of over-the-counter (OTC) Schedule V products;
21. discuss Schedule II controlled substance official prescription requirements and exceptions to the use of Schedule II controlled substance official prescriptions;
22. discuss the criteria used to place a drug product in each of the five schedules;
23. recognize commonly used controlled substances and their schedules;

24. describe procedures for reporting a theft or loss of controlled substances to DEA and DPS;
25. briefly discuss requirements for employee screening;
26. explain the procedures for disposing of the DEA registration certificate and unused order forms upon discontinuance or transfer of business;
27. describe the legal use of methadone;
28. briefly explain the special requirements for a practitioner using methadone to treat addiction;
29. discuss a pharmacist's corresponding responsibility for controlled substance prescription orders; and
30. describe DPS requirements regarding whom a practitioner may designate as an agent for the purpose of communicating a practitioner's instructions (prescription) to a pharmacist.

IV. Federal and State Food, Drug, and Cosmetic Acts:

Objectives: The candidate should be prepared to:

1. discuss the terms defined in the State and Federal Law;
2. list conditions causing a drug or device to be deemed adulterated;
3. list the conditions causing a drug or device to be deemed misbranded;
4. state the registration requirements for "Manufacturers" and "Distributors";
5. explain the illegal acts of a pharmacist under the Durham-Humphrey Amendments;
6. describe contents of a manufacturer's label;
7. state the minimum number of years prescriptions must be kept;
8. discuss FDA's recall classification system; and
9. briefly explain the requirements of FDA's Good Manufacturing Practice.

V. Texas Dangerous Drug Act:

Objectives: The candidate should be prepared to:

1. discuss the terms defined in the Texas Dangerous Drug Act;
2. list the labeling requirements for dangerous drugs dispensed by a pharmacist and by a practitioner;
3. describe the requirements of refilling a prescription;
4. list the classes of persons who may possess dangerous drugs in the performance of their official duties;
5. discuss the records a pharmacy is required to maintain under the Act;
6. describe the primary enforcing agency and legal proceedings under the Act;
7. explain forgery under the Act; and
8. describe the requirements for designation as an agent of a practitioner for the purpose of communicating a practitioner's instructions (prescription) to a pharmacist.

VI. Miscellaneous laws and regulations pertaining to Pharmacy practice:

1. Hazardous Substances:

Objectives: The candidate should be prepared to:

- ! summarize the Poison Prevention Packaging Act of 1970 and a pharmacist's responsibilities under the Act; and
- ! discuss exceptions to the child-resistant packaging requirements for specific products and patient-specific requests.

2. United States Postal Regulations:

Objectives: The candidate should be prepared to:

- ! state the U.S. Postal regulations for mailing controlled substances.

3. Texas Optometry Act:

Objectives: The candidate should be prepared to:

- ! discuss the requirements for prescribing by therapeutic optometrists (see page 493 in the Procedures, Forms and Addresses section of the T.S.B.P. law book).