Course Coordinator: Diane B. Ginsburg, Ph.D., M.S., R.Ph., FASHP  
Pronouns: She/Her/Hers  
Email: diane.ginsburg@austin.utexas.edu  
Phone: (512) 471-3631  
Office: PHR 5.110D  
Office Hours: by appointment

Course Unique Number(s): 57625 (Austin) 57630 (San Antonio)

Classroom(s): PHR 3.106

Class Days/Times:  
Lecture: Monday, 2:00 p.m. – 3:50 p.m.  
Review Session: Monday, 4:00 p.m. – 5:00 p.m.

San Antonio Faculty Coordinator: Jennifer Seltzer, Pharm.D.

Course Information

Course Description:  
Laws and rules regulate all aspects of pharmacy practice including requirements for pharmacies and pharmacists. To practice pharmacy, all pharmacists must successfully pass the Multistate Pharmacy Jurisprudence Examination (MPJE). Pharmacy law is a required course in all pharmacy curriculum. This course will cover federal and state pharmacy statutes (laws) and rules (regulations) for practicing pharmacy.

Course Prerequisites/Co-Requisites:  
Must have successfully completed all coursework through the fall semester of the P3 year.

Course Learning Objectives (CAPE Objectives):  
See attached course objectives (CAPE 1.1)

Course Success:  
Assigned readings from the textbook are required to be completed prior to each class. The class session format is a review of the topics in each section of the textbook with lecture outlines provided with PowerPoint slides. Students are expected to be prepared for lecture by completing all assigned readings each week as course material builds on prior weeks material throughout the semester. Failure to keep up with assigned readings may prevent a student from successfully passing the course.
and being prepared for the MPJE. Attendance and active participation in class discussions will provide students with the opportunity to seek clarification and readily apply the material.

**Course Website:**
This course uses Canvas, a Web-based course management system in which a password-protected site is created for each course. Canvas will be used to distribute course materials, to communicate, and to post grades. Canvas is available at [http://canvas.utexas.edu](http://canvas.utexas.edu). Support is provided by the ITS Help Desk at 475-9400 Monday through Friday 8 am to 6 pm.

**Course Communications:**
Official course communications will take place in class, through e-mail and on the course Canvas website. Students are advised to configure their Canvas settings to forward course announcements to their official e-mail address. Canvas uses only the e-mail address listed on the official University of Texas directory, so please check the University’s online directory to ensure your e-mail address is listed correctly.

**Course Video Recordings:**
A video capture system will be used in this course. The video streams are offered as a supplement to lecture attendance, not as a substitute. Therefore, if technical problems preclude recording the lecture, the lecture will **not** be re-recorded, but students are still responsible for the content of the lecture. Lecture recordings will be available to you for the balance of the semester unless otherwise specified. Do not expect to have access after the semester is over.

Faculty and students utilizing class video recordings should be careful to not compromise the privacy of either themselves or other users ([http://registrar.utexas.edu/students/records/ferpa](http://registrar.utexas.edu/students/records/ferpa)), or the rights of the presenter. Students are free to make their own recordings of lectures unless specifically prohibited from doing so by the presenter. Any additional distribution of College- or student-generated recordings (regardless of format) is prohibited without the written and signed permission of the presenter and students identifiable on the recording. Likewise, all course materials developed by the faculty member (handouts, PowerPoints, etc.) are the intellectual property of that faculty member and cannot be distributed further without the permission of that faculty member.

Viewing video-streamed recordings of lectures can be streamed on campus or can be viewed off-campus using a DSL broadband connection. Your faculty are not in a position to troubleshoot your video-streaming problems, so please do not ask them to do so; rather, you should access the LRC’s help website at [https://www.utexas.edu/pharmacy/help/](https://www.utexas.edu/pharmacy/help/) to address those problems. You will find additional information about the lecture capture system or can report technical issues at [http://sites.utexas.edu/phr-lrc/](http://sites.utexas.edu/phr-lrc/)
Course Policies

Course Grading Policies:

Course Grade:

Letter grades will be assigned according to the following scale:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>93 – 100%</td>
<td>A</td>
</tr>
<tr>
<td>90 – 92%</td>
<td>A-</td>
</tr>
<tr>
<td>87 – 89%</td>
<td>B+</td>
</tr>
<tr>
<td>83 – 86%</td>
<td>B</td>
</tr>
<tr>
<td>80 – 82%</td>
<td>B-</td>
</tr>
<tr>
<td>77 – 79%</td>
<td>C+</td>
</tr>
<tr>
<td>73 – 76%</td>
<td>C</td>
</tr>
<tr>
<td>70 – 72%</td>
<td>C-</td>
</tr>
<tr>
<td>67 – 69%</td>
<td>D+</td>
</tr>
<tr>
<td>63 – 66%</td>
<td>D</td>
</tr>
<tr>
<td>60 – 62%</td>
<td>D-</td>
</tr>
<tr>
<td>0-59%</td>
<td>F</td>
</tr>
</tbody>
</table>

Final averages at .5 or above will be rounded to the next highest grade, e.g., 92.5 = 93% = A for the course. Final averages at .4 or below will not be rounded, e.g., 92.4 = 92.4% = A- for the course.

Assignments:

Exam #1 (Unit 1) – 25 points
Exam #2 (Unit 2) – 25 points
3 IRATs (5 points each) – 15 points
Final Exam (Comprehensive) – 35 points
Course Grade – 100 Total Points

Attendance:

Class Attendance:

Class attendance is necessary for successful completion of this as course material builds on prior lectures. Unannounced IRAT quizzes will be given throughout the semester. Students must be present to take the quiz. No make-up quizzes will be permitted.

Excused Absences:

The only absences that will be considered excused are for religious holy days or extenuating circumstances due to an emergency. If you plan to miss class due to observance of a religious holiday, please let the course coordinator know at least two weeks in advance, preferably at the beginning of the semester. You will not be penalized for this absence, although you will still be responsible for any work you will miss on that day if applicable. Check with the course coordinator for details or arrangements.

Attendance at Professional Meetings:

It is the student’s responsibility to ASK permission IN ADVANCE if they plan to attend a professional meeting that would necessitate missing an exam, assignment, or other required course activity. It is at the discretion of the course coordinator as to whether to grant permission and allow the student to make up any missed work.
**Required Materials:** The required textbook for this course is *Texas and Federal Pharmacy & Drug Law, 12th Edition* (Brinkley & Caccitore). Earlier editions of the book are not acceptable as laws and rules change frequently; therefore, prior editions of the textbook may not be used for the course. It is important that you have the textbook in hand for the first class lecture on Monday, January 27.

You are responsible for all stated course objectives plus the information contained in the *Texas and Federal Pharmacy & Drug Law, 12th Edition* and for any information presented in class. In addition, there will be other information provided to you through Canvas during the semester for which you will also be responsible for knowing. It is critical that lecture material and other readings posted in Canvas be completed prior to class.

**Classroom Expectations:**

**Cell Phones & Smart Watches:** Cell phones must be put away during class and should be turned to the “off” position during all class and panel discussions. Cellphones and other electronic devices may not be used to photograph any course materials, IRATs, Exams, etc. Communication utilizing these devices is prohibited during class. We will have a break about half way through the lecture and this time may be used to catch up on texts and e-mail.

**Laptops & Tablets:** Laptop computer and tablet use during class is strictly limited to viewing lecture handouts and taking notes.

**Class Arrival:** Students are expected to arrive on time. Students arriving late will be asked to leave.

**Class Conflicts:** Please do not schedule other engagements during class time. See above for policy on excused absences.
Exam Policies

Exam Format:
Exam questions will cover learning objectives given at the beginning of each topic, course readings, and information covered during lectures. Exam questions may include: multiple choice, true/false, fill-in-the-blank, matching and/or short answer.

Exam Policies:
Three examinations will be given during the course of the semester – one at the conclusion of Unit I and Unit II, and the final exam. The final exam will be comprehensive and administered during the final exam period. In addition, three unannounced individual readiness assessment tests (IRAT) will be given during the semester. During all quizzes and exams, phones (including SmartPhones, SmartWatches or other devices such as calculators) will not be allowed. Any calculation questions will not require the use of a calculator to answer.

Exam Grading:
Grading of exams, along with statistical analysis and review of exam questions, will be the responsibility of the course coordinator, who may choose to grant credit for statistically poor questions.

Exam Return:
No examinations will be returned. Exam scores will be posted on the course Canvas site.

Exam Review:
Course coordinator will conduct one-on-one and group reviews of exams. Students who wish to review an exam or quiz should contact Dr. Ginsburg or their local faculty coordinator. The review must be done within 14 days after the grades have been posted.

Exam Reconsideration Requests
No reconsideration requests may be submitted. The course coordinator may adjust scores based on statistical data.

Final Exam Review of Old Exams:
Old exams will be not available for review prior to the final. Students should attend the review sessions for the individual exams during the semester.

Final Exam Re-Examination Policy:
There is no final exam reconsideration requests or re-examinations allowed for this course.

Request for an Alternate Exam Time:
No allowances will be made for an exam being missed, other than documented illness or emergency, or by prior approval by the Course Coordinator. An unexcused absence from an exam may result in a grade of "zero" for that exam. Any student requesting accommodation for an upcoming exam must submit the request to the course coordinator using the online form posted on Canvas® at least one month prior to the exam.
Note the new policy that an alternate exam time will be considered *only* if the student documents that they can’t be physically present on the date the exam is already scheduled.¹

**Academic Integrity:**
Students who violate University rules on academic dishonesty are subject to disciplinary penalties, including the possibility of failure in the course and/or dismissal from the University. See College Policies and Information, and University Policies and Information for more details.

**Religious Holy Days**
If you will miss a class, an examination, a work assignment or a project in order to observe a religious holy day, you must notify the course coordinator the first week of class so that arrangements for all such students can be made for the full semester.

**Services for Students with Disabilities:**
Students with disabilities may request appropriate academic accommodations from the Division of Diversity and Community Engagement, Services for Students with Disabilities at 471-6259 (voice) or 232-2937 (video phone) or [https://diversity.utexas.edu/disability/](https://diversity.utexas.edu/disability/). All University rules concerning accommodations must be followed, including the student arranging for special accommodations *prior to each examination*. In the absence of such *prearrangement*, it will be assumed that the student is not requesting special accommodations for that exam, and will be expected to take the exam with the rest of the class at the regularly scheduled exam time.

Please provide a copy of the letter to the course coordinator and the office of the Associate Dean for Academic Affairs as soon as possible after receipt.
<table>
<thead>
<tr>
<th>Units/Date</th>
<th>Lecture Topic(s)</th>
<th>Assigned Readings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/27/20</td>
<td>Orientation to the Law Course Review of <em>Texas and Federal Pharmacy and Drug Law, 12th Edition</em> (TFPDL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Overview of Syllabus and Class Procedures Introduction to the Law and Pharmacist Civil Liability (handout)</td>
<td></td>
</tr>
<tr>
<td>2/10/20</td>
<td>Federal Food, Drug, and Cosmetic Act (FDCA) and other Federal Laws (continued)</td>
<td></td>
</tr>
<tr>
<td>2/17/20</td>
<td>Federal Controlled Substances Act (FCSA) Texas Controlled Substances Act (TCSA) Corresponding Responsibility – Joel Dunn, JD, Group Supervisor – Dallas Field Division, Drug Enforcement Agency (DEA)</td>
<td>Pages B1-59 (TFPDL)</td>
</tr>
<tr>
<td>2/24/20</td>
<td>FCSA and TCSA (continued) Texas Dangerous Drug Act and Miscellaneous Texas Laws</td>
<td>Pages C1-22 (TFPDL)</td>
</tr>
<tr>
<td>2/24/20</td>
<td><strong>Exam #1 (Unit I) – EVENING – 7:00 P.M. – 9:00 P.M.</strong></td>
<td></td>
</tr>
<tr>
<td>Unit II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/2/20</td>
<td>Texas Pharmacy Act and Rules</td>
<td>Pages D1-58 (TFPDL)</td>
</tr>
<tr>
<td>3/9/20</td>
<td>Texas Pharmacy Act and Rules (continued)</td>
<td>Pages D59-102 (TFPDL)</td>
</tr>
<tr>
<td>3/16/20</td>
<td><strong>SPRING BREAK – NO CLASS</strong></td>
<td></td>
</tr>
<tr>
<td>Unit III</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/30/20</td>
<td>Complaints, Inspections, and Disciplinary Actions</td>
<td>Pages F1-39 (TFPDL)</td>
</tr>
<tr>
<td>4/6/20</td>
<td>Class A Pharmacies</td>
<td>Pages G1-54 (TFPDL)</td>
</tr>
<tr>
<td><strong>4/6/20</strong></td>
<td><strong>Exam #2 (Unit II) – EVENING – 7:00 P.M. – 9:00 P.M.</strong></td>
<td></td>
</tr>
<tr>
<td>4/13/20</td>
<td>Class A Pharmacies (continued)</td>
<td></td>
</tr>
<tr>
<td>4/20/20</td>
<td>Nonsterile and Sterile Compounding Rules Class C Pharmacies</td>
<td>Pages H1-72 (TFPDL) Pages J1-42 (TFPDL)</td>
</tr>
<tr>
<td>4/27/20</td>
<td>Class C Pharmacies (continued) Class B, D, E, F, G, and H Pharmacies</td>
<td></td>
</tr>
<tr>
<td>5/4/20</td>
<td>Class B, D, E, F, G, and H Pharmacies (continued) Final Exam Review (Units I-III)</td>
<td></td>
</tr>
<tr>
<td>May-Exam Period</td>
<td>Final Exam Week: My 13-19 Final Exam, Comprehensive (Units I-III)</td>
<td></td>
</tr>
</tbody>
</table>
Pharmacy 284E (Law)  
January 2020  
Course Objectives

Upon completion of the following units of instruction, the student will be able to demonstrate understanding and awareness of the stated laws and rules. This will be accomplished by the student’s ability to successfully respond to a series of true/false, multiple choice or short answer questions that will demonstrate understanding and awareness of all laws and rules covered in Units I-III.

UNIT I:
Introduction to the Law and Civil Liability
Federal Food, Drug, and Cosmetic Act and Other Laws Under Federal Jurisdiction
Federal and Texas Controlled Substances Acts and Texas Dangerous Drug Act

UNIT II and III:
Texas Pharmacy Act and Rules

UNIT I
Introduction to the Law and Civil Liability

1. Define and differentiate between law and ethics.
2. Explain the “law” in terms of its hierarchical forms.
3. Explain and contrast the differences between Criminal, Civil, and Administrative Law.
4. Define and explain the principle and elements of negligence.
5. Discuss the Texas Medical Liability and Insurance Improvement Act as it relates to pharmacists.

Federal Food, Drug and Cosmetic Act and Other Laws Under Federal Jurisdiction

- Pure Food and Drug Act of 1906
- Food Drug and Cosmetic Act of 1938 and its amendments (FDCA)
- Medical Device Act of 1976 and its amendments
- Drug Abuse Control Amendment
- Orphan Drug Act
- Drug Price Competition and Patent Restoration Act
- Prescription Drug Marketing Act of 1987
- Biologic Price Competition and Securities Act 2009
- FDA Safety and Innovation Act of 2012
- Drug Quality and Security Act of 2013 (Compounding Act)
- Federal Hazardous Substances Act
- Federal Hazard Communication Standard
- Poison Prevention Packaging Act
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its amendments
- Texas Privacy Law of 2012 (“Texas HIPAA”)

At the conclusion of this section, the student should be able to:
1. Define the terms drug, cosmetic, and device as outlined in the FDCA Act.
2. Define and provide examples of situations, which result in product adulteration.
3. Define and provide examples of situations, which result in product misbranding.
4. Explain the effects of the 1938 Amendments to the FDCA.
5. Explain the effects of the Durham-Humphrey and Kefauver Harris Amendments to the FDCA.
6. Provide the FDA's policy on prescription dispensing activities of pharmacists in terms prescription and non-prescription drugs.
7. Explain the federal record keeping requirements for drug distribution by pharmacists.
8. List the specific requirements for the handling of hazardous substances pursuant to the Federal Hazardous Substances Act.
9. Explain the major provisions of the Poison Prevention Packaging Act.
10. Explain the federal requirements regarding the use of prescription drug samples.
11. List the labeling requirements for ipecac.
12. Explain the regulations regarding Current Good Manufacturing Practices (CGMP) and compounding of pharmaceuticals by pharmacists.
13. Explain the content and purpose of the Medical Device Act and its amendments.
14. Describe the process by which a drug or device is recalled.
15. Specify the regulations for the use of alcohol in a pharmacy.
16. Describe and explain the major provisions of the FDA "Compounding Act” and the difference between an “Outsourcing Facility” and a compounding pharmacy.
17. Describe the difference between Texas and Federal laws and rules/regulations relating to compounding.
19. Describe the provisions of HIPAA and “Texas HIPAA” and their application to pharmacists and pharmacies.

Federal Controlled Substances Act (FCSA)

1. Describe what the Federal Controlled Substances Act does, and how its method of control differs from the old Harrison Anti-Narcotic Act.
2. Write the short title of Title II of the Act. (The short title is The Federal Controlled Substances Act.)
4. Differentiate and explain relative authority of Federal vs. State law.
5. Explain why hospitals, community pharmacies and physicians are all registered as "dispensers.”
6. State the essential requirements for pharmacies in record keeping for controlled substances.
7. State the procedure for accountability of CS’s normally administered in hospitals.
8. Describe when a pharmacy must be registered as a "distributor.”
9. State the conditions and actions necessary for a pharmacy(s) to maintain records at a location other than the registered site.
10. Describe the requirements for maintaining a DEA "Certificate of Registration" in the pharmacy.
11. State what affidavit must accompany a registration application for a new pharmacy and state the circumstances under which a purchaser of a pharmacy may file for registration prior to transfer of ownership.
12. State the physical security controls required of pharmacies.
13. Paraphrase the registration and re-registration procedures for a pharmacy.
14. Describe what is the pharmacist's best record of receipt of Schedule II drugs? Schedule III, IV and V drugs?
15. Restate the provision that requires separate registration for separate locations of business.
16. List inventory requirements using the terms: biennial inventory; Schedule II inventory; separate; exact count; 1,000 dosage units; regular inventory date; DEA notification; new pharmacies; format of inventory record.
17. State the information required on prescription records for Controlled Substances maintained in a data processing system and in a medication profile record.
18. State the conditions under which a prescription for a Schedule II drug may be partially filled beyond a 72-hour period.
19. Describe the procedure for ordering Schedule II (and I) substances from a supplier using the terms: one item/line; 10 items/order; commercial container; number of containers; finished form (i.e., strength); number of units (or volume), name of product; name and address of supplier; purchaser's name; date; copies 1, 2 and 3.
20. State how a new pharmacy obtains controlled substances order forms, the number of order forms that can be obtained at one time, and the source for obtaining additional order forms.
21. Describe the manual preparation of a DEA Form 222 including: (a) use of typewriter, pen or indelible pencil, (b) the
number of items allowed per form; (c) drug or substance ordered, (d) finished dosage form of the product, (e) number of units or volume in each container, (f) name and quantity per unit of the controlled substance contained, and (g) the name and address of the supplier from whom the controlled substances are being ordered. Describe the procedures involved if a DEA form 222 is lost or stolen.

22. Describe the procedures involved utilizing a DEA “electronic” form 222.

23. State the requirements for a pharmacist to transfer controlled substances to another DEA registrant, using the terms: Schedule II; order form; Schedules III, IV, V; records; name of product; dosage form; strength; amount; name and address of recipient; date; name of transferor. May a physician write a prescription for a Schedule II drug for himself or a family member?

24. Describe the procedures for the order and return of controlled substances. If a Schedule II item is to be returned, who supplies the DEA form?

25. List persons authorized to write a prescription for a controlled substance or to communicate the prescription to a pharmacist.

26. State the legitimate purpose of prescriptions for controlled substances and define the pharmacist’s responsibilities in ascertaining legitimacy.

27. List the requirements for information on a controlled substances prescription, using the terms: date issued; date signed; patient’s name and address; practitioner name, address, DEA #, and signature; hospital resident; institutional registration number; internal number; stamped, typed or hand printed name.

28. State the conditions under which a physician may prescribe or administer or a pharmacist may dispense narcotics for detoxification or maintenance treatment for a drug-dependent person.

29. State the regulations on refilling and partial filling of prescriptions for controlled substances.

30. Itemize the specific requirements of prescriptions for drugs listed in Schedule II; Schedule III/IV and Schedule V.

31. List the explicit labeling requirements for medications listed in Schedule II; and Schedule III/IV.

32. Describe the three options of a pharmacy in maintaining prescription files of controlled drugs.

33. State the requirements for notifying the DEA about the theft or loss of controlled substances.

34. State the procedure for disposal of controlled substances by a DEA registered disposal firm (reverse distributor).

35. Describe the provisions whereby controlled substances may be mailed pursuant to postal regulations.

36. State in which Schedule (CI - CV), commonly known controlled substances are listed.

37. Describe the DEA requirements for transmitting an electronic CS prescription (not a fax) and a faxed CS prescription.

Texas Controlled Substances Act (TCSA)

1. Compare and contrast the schedules of the Federal CSA and the Texas CSA for the following:
   a. Codeine-containing cough preparations
   b. Opium-containing antidiarrheal mixtures

2. Identify the state official whose authority is vested by the legislature to amend Texas CSA Schedules, and state two legislative actions which will prevent the administrative additions of a substance to the control schedules.

3. Compare the criteria for adding a substance to Texas CS schedules with those used in scheduling a substance under the Federal CSA.

4. State the procedure to be followed in scheduling substances at the state level with the criteria used under the Federal CSA.

5. Identify the state agency in which authority is vested by the legislature to promulgate rules and to enforce the Texas CSA as relates to pharmacists and pharmacies.

6. Compare Federal CSA and Texas CSA requirements regarding:
   a. Prescription requirements and filling of Schedule II prescriptions.
   b. Emergency dispensing of Schedule II drugs.
   c. Prescription requirements for Schedule III/IV drugs and the refilling of Schedule III/IV/V drugs.
   d. Method of filing prescriptions for controlled substances.

7. Compare Texas CSA rules with Federal CSA regulations concerning the ability of PA’s and APRNs to prescribe controlled substances.

8. Compare Federal and state CSA regulations for disposition of controlled substances owned by a registrant when his or her registration has been revoked.
9. Compare and contrast Federal and State CSA requirements for maintaining records on Schedule II and Schedule III/IV drugs; be able to compare requirements of the two Acts for dispensing or selling OTC Schedule V drugs.
10. State the period of time after the issuance of a controlled substance prescription during which it is considered a valid prescription under Texas and Federal CSA.
13. Describe the history and requirements of the Texas Official Prescription Program.
14. Describe the requirements of the Texas Prescription Drug Monitoring Program (PMP).
15. State the explicit and implicit requirements for “emergency refills” of controlled substances using the terms: quantity dispensed; required prescription information and guidelines for dispensing

Texas Dangerous Drug Act

1. Describe under what conditions a dangerous drug or a controlled substance prescription may be issued and dispensed in Texas as a result of issuance of a prescription drug order by Advance Practice Registered Nurse (APRN) or Physician Assistants (PA).
2. Describe under what conditions a dangerous drug or controlled substances prescription issued by a practitioner in a state other than Texas may be dispensed in Texas.
3. Describe under what conditions an agent of a practitioner may communicate prescriptions of a practitioner for:
   a. A controlled substance
   b. A dangerous drug
4. State under what conditions dangerous drugs may be possessed.
5. Describe the three classes of optometrists and their prescribing authority.
6. Describe under what conditions a dangerous drug prescription issued by a practitioner in Canada or Mexico may be dispensed in Texas.
7. Identify the state agency responsible for enforcing the Act.
8. List the classes of persons who may possess dangerous drugs in the performance of their official duties.
9. Explain forgery under the Act.
10. Explain the difference in regulation between a controlled substance and a dangerous drug.
11. State the explicit and implicit requirements for an emergency refill of a dangerous drug.

UNITS II and III

Texas Pharmacy Act and Rules

1. State the name of the Act under which the Texas Pharmacy Act is legally continued in existence and until what date.
2. State the general purpose of the Texas Pharmacy Act.
3. Define and distinguish between the terms: "administer," "deliver," "dispense," "distribute," and "provide."
4. Define and distinguish between the terms: "dangerous drug" and "controlled substance."
5. Define and distinguish between the terms: "medication order" and "prescription drug order."
6. Define and distinguish between the terms: "designated agent" and "pharmacy technician."
7. Define and distinguish between the eight (8) classes of pharmacy licenses.
8. Define and distinguish between (in contrast to the Federal Food Drug & Cosmetic Act) the terms: "label" and "labeling."
10. Define and distinguish between the terms: "pharmacist-intern" and "preceptor."
11. Define and distinguish between the terms: "compounding" and "manufacturing."
13. Define "practice of pharmacy."
14. Describe the composition and procedure for constituting the State Board of Pharmacy, including
15. Describe the responsibilities of the President and Executive Director of the Board.  
16. Describe the organization and financing of Board operations, including: (a) the minimum number of Board meetings, (b) compensation of Board members, the Executive Director, and other Board staff, (c) quorum rule, (d) Board meetings "open to the public" vs. "executive session."  
17. State the name of the Act with which the Board must be in compliance in adopting rules and the nature of rules the Board is specifically restricted from adopting.  
18. Describe the responsibilities and authority of the Board:  
   a. For the regulation of the practice of pharmacy, including: licensing by examination and reciprocity; standards for recognition and approval of degree requirements; requirements for internship; suspension, revocation, fining, reprimanding, or restriction of licenses; enforcement of the Act and rules.  
   b. Specifications of conditions under which a pharmacist may administer medications.  
   c. For the practice of pharmacy for prescription drugs and devices, including: right to seize drugs and devices, persons and situations exempted from Board regulation, specification of minimum standards.  
   d. For joining professional organizations and associations.  
   e. Adoption of rules regulating a prescription drug order or medication order transmitted by electronic means.  
   f. For issuance of subpoenas and obtaining injunctions.  
   g. For the filing of written annual reports.  
   h. For the fiscal operation of the Board, including place of deposit of Board revenue (fees and fines), legislative appropriation required for expenditure, general uses of revenue, and accountability of the Board for revenue.  
   i. For revenue sources other than fees and fines.  
   j. For investigations and the gathering of evidence, including the Board's authority with regard to: subpoenas, oaths, taking of testimony, suit for injunctive relief.  
   k. For cooperative relationship with other state or federal agencies.  
   l. For the maintenance of an office, records of proceedings and information files about complaints.  
   m. For internal and external advisory committees.  
   n. For Board investigative files and related information being confidential and how they may be disclosed.  
   o. For establishing rules for the use and duties of pharmacy technicians and the specific restriction from making rules.  
   p. To be represented by legal counsel.  
   q. To furnish information (under the Texas Public Information Act) from its investigative files.  
   r. For Board employees to possess dangerous drugs and controlled substances.  
   s. For commissioning employees as "peace officers" with the powers, privileges and immunities of peace officers.  
   t. For informing consumers about Board functions and procedures for filing and resolving complaints.  
19. Describe the authority and procedure for the Board to carry out administrative inspections, defining and using the terms: "facility," "written notice of inspection authority," "inspection warrant," "consent of the owner," "imminent danger to the public health and safety," "probable cause," "reasonable time to comply," and "authority to inspect records."  
20. List those persons (and conditions) under which they may dispense and/or distribute prescription drugs, who are not licensed pharmacists.  
21. Describe the penalty for practicing pharmacy without a license.  
22. Describe the conditions for pharmacist-intern registration and the continuance of that registration.  
23. State the qualifications for licensing by examination.  
24. Describe the authority of the Board and procedure for creation and administration of the licensing exam using such terms as: content and subject matter, consultant in the preparation and grading, sole discretion, notification of exam results, practical experience, standards for internship, qualifications of preceptors.  
25. State the qualifications for licensing by reciprocity and a condition required of the state from which a reciprocity applicant applies.
26. State the conditions for display of a pharmacist's license.
27. Describe the required procedure for pharmacist license renewal, including: expiration date, renewal filing, fee for late filing (within 90 days and after 90 days up to 1 year), filing for renewal after 1 year, penalty for practicing pharmacy without current license renewal, prohibition of duplicating license or renewal certificate.
28. Describe the continuing education requirements for renewing a pharmacist’s license.
29. Describe the procedures for placing a pharmacist's license on an inactive status.
30. State the grounds for disciplinary action by the Board in refusing to issue a license or for renewal; assess a penalty, reprimanding, revoking, restricting, or suspending any license (pharmacist or pharmacy) offered by the Board.
31. State the name of the Act in addition to the Texas Pharmacy Act, which governs the procedure of the Board in any disciplinary action.
32. Describe the penalties, which the Board may invoke and the procedure for reinstatement of a license, which has been revoked or restricted.
33. State and clarify certain conditional consequences of Board disciplinary action, including: criminal prosecution in addition to Board prosecution, judicial review of Board action under the substantial evidence rule, and limitations to the type of disciplinary action which may be taken by the Board for violation of Board rules.
34. State the eight (8) classes of pharmacy licenses and their individual degree of required supervision by a pharmacist and the laws and rules governing operation of each class of pharmacy.
35. State the authority of the Board in determining the class of pharmacy to which an applicant may be assigned and the special restriction of the Board establishing a ratio for pharmacy technicians employed in Class C pharmacies.
36. State the authority of the Board to inspect facilities licensed under the Act and the exemption regarding licensure fees for Class D pharmacies operated by state or local governments.
37. Describe:
   a. the procedure for making application for a pharmacy license, including: specific information to be included in the application; and
   b. the conditions after licensure of a pharmacy, including: Board authority for establishing minimum standards for professional responsibility, separate licensing for separate specific locations, display of the license, display of the word "pharmacy," and display of pharmacists' licenses employed in the pharmacy.
38. State the authority of the Board regarding renewal of pharmacy licenses, expiration date for pharmacy licenses, and action to be taken in the event that renewal is not filed on time.
39. State items required of a pharmacy license holder to notify the Board of within what time frame; state the items required of a pharmacist license holder to notify the Board of within what time frame.
40. Describe the conditions under which dangerous drugs may be "administered" or "provided" through a practitioner, using terms such as: qualified and properly trained persons; in the physician's office; the immediate needs of the physician's patients; standing orders; retailing of drugs; facilities with Class D license; compliance with laws relating to the practice of medicine, nursing, pharmacy and Texas or federal drug laws; supplied in a suitable container, labeled in compliance with applicable drug laws, and provision for labeling at the time of "provision" of a drug.
41. State the unlawful use of the word "pharmacy," the title "Registered Pharmacist," or "R.Ph."
42. State and clarify the burden of proof for any claimed exemption or exception under any proceeding by the Board under the Act and the limitation of Board employees and persons under their supervision for liability while engaged in the lawful enforcement of the Act.
43. State how the Board may establish fees to cover the cost of administering The Pharmacy Act.
44. Describe the conditions under which a pharmacist may substitute a different manufacturer's or distributor's drug product or different dosage form than that prescribed, using such terms as: intent of the legislature to save consumer money, may dispense, generically equivalent, pharmaceutically equivalent, therapeutically equivalent, and biologically similar drug products.
45. State what information a pharmacy must provide to consumers under the provisions of the Texas Pharmacy Act.
46. State the conditions under which a pharmacist may dispense an emergency refill for a dangerous drug or a schedule III-V controlled substance.
47. Discuss the conditions under which pharmacy records, that are "confidential records", may be released.
48. Discuss the procedure by which prescription drugs are disposed of or destroyed.
49. Describe the conditions where a pharmacist may become involved in “medication management” and administration of vaccines.
50. State the Board's rules concerning access to public information and the conduct of hearings.
51. Describe the procedures used by the Board to initiate and take disciplinary action against a licensee.
52. List the grounds for disciplinary action against a pharmacist for acts relating to:
   a. unprofessional conduct
b. gross immorality
   c. fraud, deceit and misrepresentation

53. List the grounds for disciplinary action against a pharmacy for failing to establish and maintain effective controls against diversion of prescription drugs.

54. Explain the effect upon a license of the imposition of penalties against the license.

55. State the manner by which an Order of the Board may be appealed.

56. Describe the procedures for reissuance or removal of restrictions of a license.

57. Describe the procedures for adopting, repealing, or amending rules.

58. List the licensing requirements for pharmacists relating to:
   a. Definitions
   b. Education and Age
   c. Internship
   d. Intern Duties
   e. Preceptor Requirements
   f. Examination Requirements
   g. Reciprocity Requirements
   h. Fee Requirements
   i. Requirements for Application for a Pharmacist License which has expired

59. Explain the general procedures/requirements for all classes of pharmacies relating to:
   a. Pharmacy License Application
   b. Change of Location and/or Name
   c. Change of Managing Officers
   d. Change of Ownership
   e. Closed Pharmacies
   f. Pharmacy License Fees
   g. Change of Pharmacist Employment
   h. Return of Prescription Drugs
   i. Prescription Pick up Locations
   j. Fire of Other Disaster
   k. Pharmacy License Renewal
   l. Notification of Theft or Loss of a Controlled Substance
   m. Inventory Requirements for Controlled Substances and Certain Dangerous Drugs
   n. Time Limit for Filing a Complaint
   o. Administrative Actions as a Result of a Compliance Inspection
   p. Drug recalls

60. State the operational standards for Class A, B, C, D, E, F, G, & H pharmacies.

61. State the specific responsibilities and duties of the pharmacist-in-charge and staff pharmacists for Class A, B, C, D, E, F, G, & H pharmacies.

62. List the requirements for pharmacy technicians relating to qualifications, duties and training in Class A, B, and C pharmacies.

63. Explain the requirements for maintenance of records in Class A, B, C, D, E, F, G, & H pharmacies.

64. List labeling requirements for prescription drugs in Class A, B, C, D, E, F, G, & H pharmacies.

65. Describe drug prepackaging requirements in Class A, B, C, and D pharmacies.

66. State the allowable ratio of pharmacists to pharmacy technicians and trainees in all classes of pharmacies.

67. Describe the requirements for dispensing prescriptions, including provisions for patient counseling and drug information.

68. Explain the maintenance of prescription records in a manual system relating to:
   a. Filing
   b. Refills
   c. Refill authorization
   d. Transfer of Rx information

69. Explain the maintenance of prescription records in a data processing system relating to:
   a. Filing
   b. Records of dispensing
   c. Refill authorization
   d. Transfer of Rx information
70. Describe the distribution of drugs in a hospital pharmacy in the absence of a pharmacist:
   a. Pursuant to a medication order.
   b. Pursuant to floor stock.
71. Describe the supplying of drugs from hospital:

   Emergency rooms

   Radiology departments

72. Describe the requirements of for compounding and preparation of non-sterile and “sterile products” in Class A, C and E pharmacies.
73. Explain the supplying of drugs for postoperative use in ambulatory surgical centers.
74. Explain the rules governing the operation of “automated dispensing systems” in Class A and C pharmacies.
75. Describe the specific types of “remote pharmacy services” that may be provided by Class A and C pharmacies.
76. List the registration requirements for pharmacy technicians and pharmacy technician trainees.
77. Describe the disciplinary actions that may be taken against pharmacy technicians and trainees.
78. Describe the requirements for pharmacists administering vaccinations and immunizations.
79. Explain the provisions of law and the rules which allow pharmacists to provide “Emergency Refills.”
80. Describe the conditions which allow a pharmacist to sign a prescription drug order for dangerous drugs.
81. Explain the TSBP policy regarding prescriptions of deceased practitioners.
82. Explain the present legal status of telemedicine in Texas and the legality of prescriptions issued by a practitioner practicing “telemedicine.”