



Syllabus: Pharmacy Law

Course Number: PHRA 1202

Semester & Year: FALL 2023

Instructor Information

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Office Hours: See posting in office #123 window for current office hours by appointment.

Required Textbook Information

- The Pharmacy Technician Foundations and Practices 3rd ed. by Mike Johnston, CPhT ISBN# 978-0-13-289-7594
- The Pharmacy Technician Lab Manual and Workbook 3rd ed. by Mike Johnston CPhT, ISBN# 978-0-13-289809-6

Course Description

This course provides an overview of federal and state laws governing the practice of pharmacy. The legal and ethical constraints governing pharmacy technician and the pharmacist responsibilities in practice settings are discussed.

Student Learning Outcomes for the Course

Upon successful completion of the course, the student will be able to:

1. **Distinguish between the responsibilities of pharmacy technicians and pharmacists in pharmacy settings.**
2. **Apply and explain federal and state laws that govern pharmacy practice and the Code of Ethics guiding the practice of pharmacy.**

Student Requirements for Completion of the Course

Students must complete assigned homework, quizzes, and exams with an average of 70% or greater.

Student Assessment

Student's final grade for the semester will be determined by the following:

Classwork/ Homework Assignments/Quizzes	20%
Pharmacy Laws Project	30%
Workbook Assignments	15%
Chapter Exam	15%
Final Exam	20%
	<hr/>
	100%

Grading Scale

Grade	
A	90-100

B	80-89
C	70-79
D	60-69
F	59-below

Class Schedule and Assignments

Class will meet as scheduled: **Monday, Tuesday, Wednesday and Thursday 0900-1000**

Assignments, quizzes, and the 1 exam will be assigned by instructor in class. Homework assignments should be turned in on the class day following the date of assignment or as advised by the instructor. Quizzes may or may not have prior notification, and the student is responsible for staying up to date on reading materials. Students are expected to participate in class discussions, group activities, and presentation activities.

	MONDAY 0900-1000	TUESDAY 0900-1000	WEDNESDAY 0900-1000	THURSDAY 0900-1000
WEEK 1	Oct. 16, 2023 Course introduction, syllabus review and introductions	Oct. 17, 2023 <i>Apply and explain federal and state laws that govern pharmacy practice and the Code of Ethics guiding the practice of pharmacy.</i> 1 hour lecture – Overview of Law CH 4	Oct. 18, 2023 1 hour lecture – Criminal, Civil, and Administrative Law CH 4	Oct. 19, 2023 <i>Explain the role of the Texas State Board of Pharmacy (TSBP) and other regulatory agencies.</i> 1 hour lecture- Centers for Disease Control and Prevention CH 4
WEEK 2	Oct. 23, 2023 <i>Explain the role of the Texas State Board of Pharmacy (TSBP) and other regulatory agencies.</i> 1 hour lecture- Centers for Disease Control and Prevention – CH 4	Oct. 24, 2023 <i>Explain the role of the Texas State Board of Pharmacy (TSBOP) and other regulatory agencies.</i> 1 hour lecture – Centers for Medicare and Medicaid Services – CH 4	Oct. 25, 2023 <i>Explain the role of the Texas State Board of Pharmacy (TSBOP) and other regulatory agencies.</i> 1 hour lecture – Drug Enforcement Administration – CH 4	Oct. 26, 2023 <i>Explain the role of the Texas State Board of Pharmacy (TSBOP) and other regulatory agencies.</i> 1 hour lecture – Food and Drug Administration – CH4
WEEK 3	Oct. 30, 2023 <i>Explain the role of the Texas State Board of Pharmacy (TSBOP)</i>	Oct. 31, 2023 QUIZ & Other assessments	Nov. 1, 2023 <i>Summarize important points</i>	Nov. 2, 2023 <i>Summarize important points</i>

	<p><i>and other regulatory agencies.</i> 1 hour lecture – The Joint Commission, Occupational Safety and Health Administration, and State Boards of Pharmacy – CH 4</p>		<p><i>of federal acts that affect the pharmacy profession.</i> 1 hour lecture FEDERAL PHARMACY LAW The Pure Food and Drug Act of 1906 – CH 4</p>	<p><i>of federal acts that affect the pharmacy profession.</i> 1 hour lecture FEDERAL PHARMACY LAW The Sherley Amendment 1912 and The Food, Drug, and Cosmetic Act of 1938. CH 4</p>
WEEK 4	<p>Nov. 6, 2023</p> <p><i>Summarize important points of federal acts that affect the pharmacy profession.</i></p> <p>1 hour lecture FEDERAL PHARMACY LAW The Durham-Humphrey Amendment of 1951 and The Federal Hazardous Substance Labeling Act of 1960 – CH 4</p>	<p>Nov. 7, 2023</p> <p><i>Summarize important points of federal acts that affect the pharmacy profession.</i></p> <p>1 hour lecture FEDERAL PHARMACY LAW The Kefauver-Harris Amendment of 1962 and The Comprehensive Drug Abuse Prevention and Control Act of 1970 – CH 4</p>	<p>Nov. 8, 2023</p> <p><i>Summarize important points of federal acts that affect the pharmacy profession.</i></p> <p>1 hour lecture FEDERAL PHARMACY LAW The Comprehensive Drug Abuse Prevention and Control Act of 1970 – CH 4</p>	<p>Nov. 9, 2023</p> <p><i>Summarize important points of federal acts that affect the pharmacy profession.</i></p> <p>1 hour lecture FEDERAL PHARMACY LAW The Comprehensive Drug Abuse Prevention and Control Act of 1970 – CH 4</p>
WEEK 5	<p>Nov. 13, 2023</p> <p><i>Summarize important points of federal acts that affect the pharmacy profession.</i></p> <p>1 hour lecture FEDERAL PHARMACY LAW</p>	<p>Nov. 14, 2023</p> <p><i>Summarize important points of federal acts that affect the pharmacy profession.</i></p> <p>1 hour lecture FEDERAL PHARMACY LAW</p>	<p>Nov. 15, 2023</p> <p><i>Summarize important points of federal acts that affect the pharmacy profession.</i></p> <p>1 hour lecture</p>	<p>Nov. 16, 2023</p> <p><i>Summarize important points of federal acts that affect the pharmacy profession.</i></p> <p>1 hour lecture</p>

	The Poison Prevention Packaging Act of 1970 and The Occupational Safety and Health Act of 1970 – CH 4	The Poison Prevention Packaging Act of 1970 and The Occupational Safety and Health Act of 1970 – CH 4	FEDERAL PHARMACY LAW The Drug Listing Act of 1972, The Medical Device Amendment of 1976 and The Orphan Drug Act of 1983 CH 4	FEDERAL PHARMACY LAW The Drug Listing Act of 1972, The Medical Device Amendment of 1976 and The Orphan Drug Act of 1983 CH 4
OFF WEEK	Nov. 20, 2023 Thanksgiving Break	Nov. 21, 2023 Thanksgiving Break	Nov. 22, 2023 Thanksgiving Break	Nov. 23, 2023 Thanksgiving Break
WEEK 6	Nov. 27, 2023 <i>Summarize important points of federal acts that affect the pharmacy profession.</i> 1 hour lecture FEDERAL PHARMACY LAW The Drug Price Competition and Patent Term Restoration Act of 1984, The Prescription Drug Marketing Act of 1987 and The Anabolic Steroid Control Act of 1990 – CH 4	Nov. 28, 2023 <i>Summarize important points of federal acts that affect the pharmacy profession.</i> 1 hour lecture FEDERAL PHARMACY LAW The Drug Price Competition and Patent Term Restoration Act of 1984, The Prescription Drug Marketing Act of 1987 and The Anabolic Steroid Control Act of 1990 – CH 4	Nov. 29, 2023 <i>Summarize important points of federal acts that affect the pharmacy profession.</i> 1 hour lecture FEDERAL PHARMACY LAW The Omnibus Budget Reconciliation Act of 1990, The Dietary Supplement Health, and Education Act of 1994 – CH 4	Nov. 30, 2023 <i>Summarize important points of federal acts that affect the pharmacy profession..</i> 1 hour lecture FEDERAL PHARMACY LAW The Health Insurance Portability and Accountability Act of 1996, The Food and Drug Administration Modernization Act of 1997, and The Drug Addiction Treatment Act of 2000 CH 4
WEEK 7	Dec. 4, 2023 <i>Summarize important points of federal acts</i>	Dec. 5, 2023 <i>Summarize important points of federal acts</i>	Dec. 6, 2023 TEST	Dec. 7, 2023 <i>Apply and explain federal and state laws</i>

	<p><i>that affect the pharmacy profession.</i></p> <p>1 hour lecture FEDERAL PHARMACY LAW The Medicare Modernization Act of 2003 and USP Chapter <797> - CH 4</p>	<p><i>that affect the pharmacy profession.</i></p> <p>1 hour lecture FEDERAL PHARMACY LAW The Combat Methamphetamine Epidemic Act of 2005, The Medicaid Tamper- Resistant Prescription Pad Law of 2008 CH 4</p>	<p><i>Summarize important points of federal acts that affect the pharmacy profession.</i></p> <p>1 hour lecture FEDERAL PHARMACY LAW The Affordable Care Act of 2010 – CH 4</p>	<p><i>that govern pharmacy practice and the Code of Ethics guiding the practice of pharmacy.</i></p> <p>1 hour lecture ETHICS AND THE PHARMACY TECHNICIAN CH 4</p>
WEEK 8	<p>Dec. 11, 2023</p> <p><i>Distinguish between the responsibilities of pharmacy technicians and pharmacists in pharmacy settings.</i> 1 hour lecture Supplemental Handout</p>	<p>Dec. 12, 2023</p> <p><i>Explain the processes for new drug approval and removing drugs from the market.</i> 1 hour lecture Supplemental Handout</p>	<p>Dec. 13, 2023</p> <p><i>Explain the processes for new drug approval and removing drugs from the market.</i> 1 hour lecture Supplemental Handout</p>	<p>Dec. 14, 2023</p> <p>Final Exam</p>

COURSE OUTLINE

- History of pharmacy law (CH 4)
- Legal and ethical terms and principles in pharmacy practice (CH 4)
- Liability in practice (Internet)
- Regulatory Agencies including the U.S. Justice Department, DEA, State Board of Pharmacy, and others (CH 4)
- Pharmacy inspections/categories (A, B, C, D, E)
- Drug approval process (CH 38 and Google Drive)
- Process for withdrawing a medication from the market (CH 11)
- Patient confidentiality and HIPAA (CH 4)
- Federal acts that affect pharmacy practice, including, but not limited to, OBRA, HIPAA, Food, Drug, and Cosmetic Act, Controlled Substances Act of 1970, Poison Prevention Act, and Tamper Resistant Packaging Act (CH 4 and Internet)
- Professional Code of Ethics (CHs 2, 4, 8, and 9)

- Lawsuits involving medications, pharmaceutical manufacturers, pharmacists, pharmacies, and medication errors (Internet and CH 35)

Student Behavior Policies and Procedures Student Behavior Policies and Procedures

Please refer to the Texarkana College Student Handbook for the full list of rules, policies, and procedures related to student conduct. In addition, please note and initial understanding of the following policies and procedures related to student misconduct:

ADDENDUM

Texarkana College strives to provide a safe and comfortable learning environment free of abuse and distractions. At all times, students are required to practice courteous, respectful, and cooperative behavior. When students violate standards of conduct or act in a manner that disrupts the learning process, it is not fair to the students who do act appropriately. Students who do not comply with the policies of the program, college, and/or clinical facilities will face disciplinary action to encourage compliance.

- Students are to address all instructors, personnel, visitors, guests, and classmates with respect and in a professional manner.
- Disrespecting instructors will not be tolerated. Students will be written up and sent home.
- Food and drink during classroom hours is at the discretion of the instructor.
- NO food/drink items are allowed in carpeted rooms or computer labs.
- Cursing, foul or derogatory language will not be permitted on campus.
- Use of electronic devices, including cell phones, are prohibited during class.

Clinical rotations are considered a class. These must be set on silent or turned off.

- No talking during lectures, exams, or when working on assignments.
- Students are expected to dress in a professional manner for class. NO pajamas, slippers, or clothing with questionable coverage is allowed (i.e. - cleavage, abdomen, and bottom should be covered at all times).
- Cheating will not be tolerated. Students caught cheating will be subject to disciplinary action after investigation by the Dean of Students. Proven violations will result in the student being dropped from the class with an "F" average.
- No children allowed. A student may not for any reason bring a child to class with them. NO EXCEPTIONS.
- Family members or other acquaintances are not allowed in the classroom or at practicum sites.
- Texarkana College is a tobacco free campus. No tobacco products are allowed.
- Students must strictly follow the Health Occupations drug and alcohol policy.
- Patient confidentiality will be secure at all times. No patient identifying information will be taken from the practicum site.

Write- Up Offenses

- Personal use of electronic devices including cell phones
- Improper dress and personal appearance
- Leaving class without permission
- Failure to follow procedures/policies
- Sleeping during class (Attendance policy will apply)

- Failure to follow the grooming and dress codes for the classroom
- Failure to notify instructor of absence from a clinical experience before the scheduled start time

Write up offenses that will include sending student home. (Attendance policy will apply).

- Profanity anywhere in the building or on campus
- Lack of cooperation with instructors
- Disruptive/unprofessional behavior
- Being unprepared for class
- Failure to adhere to the drug and alcohol policy (Violators may be removed from the program)
- Bringing a child to class
- Failure to follow the grooming and dress codes for clinical experiences. **This includes wearing artificial nails, nail polish (including clear) or overlay to a clinical site.**
- Meeting with a family member or acquaintance during class time or at clinical.
- Violations of patient confidentiality (HIPAA)

• Actions that pose actual or potential harm to patients (May result in removal from the program) Individual counseling and a write-up will occur with all violations; the student may be placed on probation from the program. All counseling sessions and write-ups will be documented in the student's permanent record. The student will be provided an opportunity to document their account of the violation(s), and this documentation will be retained in the student's record as well. The disciplinary measures implemented are at the discretion of the Program Coordinator and in accordance with written program policies described within this handbook and the **Texarkana College Student Handbook. When a student accrues four (4) write-ups/counseling sessions, he/she may be removed from the program without eligibility for re-entry.**

The student has access through the academic grievance policy for an appeals process for any disciplinary action the student feels is unwarranted or unfair. The academic grievance policy is outlined in the Texarkana College Student Handbook.

ABSENTEE POLICY

Texarkana College's absentee policy allows instructors to withdraw a student from a course due to excessive absences. If a student leaves and returns during class or leaves the class before the class is over, he/she may be considered absent. Three tardies constitute one absence. It is the student's responsibility to check the syllabus for each instructor's tardy policy.

In some workforce/vocational areas, such as nursing and cosmetology, certification requirements necessitate an absentee policy that is more stringent than the institutional policy. In these instances, the matter of certification takes precedence over local policies, since certification policies are established by the State of Texas.

Faculty members **are not** obligated to provide opportunities for students to make-up missed assignments and tests as a result of a student's absence from class. The institution is not required to take attendance with the exception of workforce/vocational areas, where certification requirements require taking attendance. However, experience demonstrates that regular attendance enhances academic success. As such, students are expected to attend each meeting of their registered courses.

A student should not stop attending a class without formally withdrawing from the course by the institutions published Last Day for Students to Drop. If a student stops attending class after the published Last Day for Students to Drop, the student may receive a grade of “F” in the class. The instructor will submit the last date of attendance for students receiving a grade of “F” or “W”.

Withdrawal from a course(s) **may** affect a student’s current or future financial aid eligibility. Students should consult the Financial Aid Office to learn both short and long term consequences of a withdrawal.

EXCUSED ABSENCES

A student’s absence due to school trips and/or school business will not be counted against a student’s allowable number of absences. Military duty and absences for Holy Days (FBD LEGAL) are covered in a separate section of the catalog and the student handbook. These are the only excused absences that are considered by Texarkana College. Responsibility for work missed for any absence is placed on the student. Instructors are required to allow students to make up work missed if the absence is due to military duty* or religious holy days when students follow the correct notification procedures. Instructors are not required to allow students to make up work for absences due to other reasons. Make-up policies are listed in each individual instructor’s syllabus.

**Students interested in Health Occupations should check with the division chair prior to entering the program.*

ONLINE/HYBRID COURSE ABSENCES

Absence in an online course is defined as the lack of an active post or submission within the course including discussion board posts, written assignments, and tests. This standard will be used to determine all absentee issues, including but not limited to, 12th Day Census Reports, last date of attendance, and involuntary withdrawal from a course due to absences. All online students must complete an Enrollment Verification activity within the first week of class (activity depends upon the professor); otherwise the professor may drop the student for not having attended. Students must complete at least one activity in their online class per week. Each week in which a student does not complete an activity will be counted as an absence.

If a student is taking a hybrid course, and it does not meet during the first week of class, the student must also complete an Enrollment Verification activity within the first week of class; otherwise the student may be dropped for not having attended.

MAXIMUM ALLOWABLE ABSENCES

After official registration, the following number of unexcused absences will be the maximum allowable before a student may be dropped from the class. Mandated program certification requirements detailed for certain programs regarding the maximum allowable unexcused absences takes precedence over the following information.

Workforce Classes

Day Classes	Evening Classes
Class meets: 5 days a week (MTWRF) The instructor may withdraw a student from a course if absences exceed five (5) up until the	Class Meets: 4 evenings a week (MTWR) The instructor may withdraw a student from a course if absences exceed five (5) up until the

<p>published Last Day for Students to Drop. Absences that exceed this number after the drop day may result in the student receiving an “F” in the program for that semester. Three tardies count as one absence. You are considered tardy from the designated class start time through the first 15 minutes of class. After that you will be counted absent.</p>	<p>published Last Day for Students to Drop. Absences that exceed this number after the drop day may result in the student receiving an “F” in the program for that semester. Three tardies count as one absence. You are considered tardy from the designated class start time through the first 15 minutes of class. After that you will be counted absent.</p>
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Students are allowed 5 class absences. After 5 absences, the student is subject to being dropped from the course. Attendance will be taken at the beginning of each class period. If a student is up to 15 minutes late to class, a tardy will be given. Students who are late will be required to sign in to the instructor’s attendance folder with the time of arrival. After 3 tardies, an absence will be assigned.

Make-up Policy

Students are responsible for contacting the instructor to discuss content and makeup work that is missed during an absence. If an exam is missed, the student must make-up the exam within five (5) class days upon their return. Homework that was assigned prior to a student absence should be turned in on the first day back to class. Late homework assignments will not be accepted, and a grade of zero will be given.

Academic Integrity Statement

Scholastic dishonesty, involving but not limited to cheating on a test, plagiarism, collusion, or falsification of records will make the student liable for disciplinary action after being investigated by the Dean of Students. Proven violations of this nature will result in the student being dropped from the class with an “F”.

This policy applies campus wide, including TC Testing Center, as well as off-campus classroom or lab sites, including dual credit campuses. This information can be found in the Student Handbook at <https://texarkanacollege.edu>.

Disability Act Statement

Texarkana College complies with all provisions of the Americans with Disabilities Act and makes reasonable accommodations upon request. Please contact Larry Andrews at 903.823.3283, or go by the Recruitment, Advisement, and Retention Department located in the Administration building for personal assistance.

Financial Aid:

Attention! Dropping this class may affect your funding in a negative way! You could owe money to the college and/or federal government. Please check with the Financial Aid office before making a decision.

Security

Please keep your vehicle locked whenever you are away from it. Make sure you don’t leave any valuables in plain sight (purse, phone, laptop). We want you to be safe. You

must acquire a TC parking permit and display it in your vehicle. You must also have a TC student ID badge and keep it with you at all times.

Campus police EMERGENCY line: (903) 798-3330

Please add this number to your contacts.

Texarkana College Student Counselor: (903) 823-3143

Suicide Hotline: 1-800-273-8255

STUDENT RETENTION AND SUPPORT

A student retention specialist is available for every student enrolled in the Pharmacy Technician Program. Karen Holt will help you with study skills, referral to Student Support Services, resume writing, job interview skills, direction to social support programs, and other services. Mrs. Holt can be contacted at Karen.holt@TexarkanaCollege.edu or at 903-823-3351. Her office is located in the Health Science Building 2nd floor office # 351.

STUDENT SUPPORT SERVICES' INFORMATION

Student Support Services is a federally funded program designed to give a helping hand to Texarkana College students who show potential for success in college, but who need assistance in their efforts. Students entering the program have a variety of needs encompassing economic, academic, cultural, and handicapped challenges. Student Support services can help you by offering career information, tutoring, study skills, and college transfer information.

Student Support Services
Career Education Center, Room 106
2500 N. Robison Road
Texarkana, Texas 75501

903-823-3381

Office Hours
8:00am to 5:00pm, Monday – Friday

Basic Needs Security Statement

Any student who has difficulty affording groceries or accessing enough food to eat every day, or who lacks a safe and stable place to live and believes this may affect their performance in this course or ability to remain in school, is urged to contact Tonja Blase, Director of Student Retention, at 903.823.3349 for support. Furthermore, please notify the professor if you are comfortable in doing so. This will enable them to provide any resources that they may possess.

DISCLAIMER:

TC does not discriminate on the basis of race, color, national origin, sex, disability or age in its programs or activities. The following person has been designated to handle inquiries regarding the nondiscrimination policies: Human

Resources Director, 2500 N. Robison Rd., Texarkana, TX, 75599, (903) 823-3 ,
human.resources@texarkanacollege.edu

SYLLABUS AGREEMENT

If you have any questions about this syllabus or the course in general, ask the instructor before you sign this document.

PHRA 1202
Pharmacy Law

I, _____, (print name) have read the course syllabus), the course outline and schedule, course grading requirements and methods of evaluation, as well as had each explained to me by the instructor either verbally, or by email on _____.

By signing this form, I agree to comply with the classroom/online policies, expectations, and rules listed and accept the outline for this class.

Signature

Date

Print Name

Received by the instructor on: _____
Date