

**SYLLABUS**  
**Pharmacy Law and Ethics**  
**PHAR 621**  
**(Fall Semester, 2014)**

This syllabus is not to be construed as a contract with the student and is subject to change.

The School of Pharmacy reserves the right to change the course syllabus. *The School should notify the students through the course notification system or by an email preferably through the Blackboard system.*

*Materials used in this class may be copyrighted and should not be shared with individuals not enrolled in this course.*

Course meeting days and time	Mondays 4:30pm-6:00pm
Location	
Team Leader / Instructor	Brian A. Gallagher, RPh, JD
Office	144
Phone	304-696-7330 or 301-691-8982
Email	gallagherb@marshall.edu
Office hours	By appointment

Faculty	Email	Office	Phone Number	Office Hours / Appointments accepted?
Tamela J. White, BSN, JD, MPH	pharma@farrell3.com	Farrell, White & Legg, PLLC, 914 5 <sup>th</sup> Ave, Huntington, WV	304-522-9100	By appointment
Michael J. Farrell, JD	pharma@farrell3.com	Farrell, White & Legg, PLLC, 914 5 <sup>th</sup> Ave, Huntington, WV	304-522-9100	By appointment
Erik W. Legg, JD	pharma@farrell3.com	Farrell, White & Legg, PLLC, 914 5 <sup>th</sup> Ave, Huntington, WV	304-522-9100	By appointment

**Student:** If the instructor accepts appointments, then please email the instructor for availability. The student can expect the instructor to respond to E-mails and phone messages within 72 hours.

**Course Description:** *An applied analysis of federal and West Virginia state law and ethical standards in the practice of Pharmacy and Pharmaceutical Care.*

**Prerequisites:** P2 Standing

**Text Books:**

**Required:**

1. *Pharmacy Laws and Legislative rules of West Virginia Governing the Practice of Pharmacy & Controlled Substances Act, 2013 Ed., West Virginia Board of Pharmacy, Lexis Nexis.*
2. *Pharmacy Practice and the Law, 7<sup>th</sup> Ed., Richard A. Abood (with online access), Jones & Barnett Learning, 2013.*
3. *The American Pharmacists Association Code of Ethics (2013).*

**Course Objectives:** *Instructor added (5 to 7 total)*

Number	Objective	Linkage to MUSOP Abilities (list ability numbers)	How Assessed
1	Identify legal and ethical issues in the practice of Pharmacy;	13	IRAT, GRAT, discussion and class participation, midterm, comprehensive final.
2	Identify the resources available in addressing and evaluation legal and ethical issue in the practice of pharmacy; and	10, 13	IRAT, GRAT, discussion and class participation, midterm, comprehensive final.
3	Apply and comply with federal and state governing law and regulations for the Practice of Pharmacy in the United States and specifically West Virginia	10, 63	IRAT, GRAT, midterm, discussion and class participation comprehensive final.

**Schedule of Activities:** *(Instructor: List each day class meets, exam schedule, major project schedule, map learning outcomes to course objective or MUSOP abilities. Mark each major assessment with as asterisk (\*))*

Date	Meeting Format	Meeting Topic and pre-work	Course Student Learning Outcomes	Instructor
August 25, 2014		Class overview and intro to law <i>Pre-work:</i> Review slides and read <u>Abood</u> pp 1-16 and 39-60	-Describe the US legal system -Explain the sources of law -Understand key components of the Food Drug and Cosmetic Act	Gallagher
September 1, 2014	No Class	Labor Day Recess		
September 8, 2014		FDCA <i>Pre-work:</i> Review slides and read <u>Abood</u> pp 60-105, 236-241, 302-308 and 317	-Understand additional components of the FDCA -Articulate the corresponding responsibility rule -Explain certain enforcement activities	Legg

September 15, 2014		FDA	-Understand drug product selection and generic substitution -Master laws regulating dispensing -Discuss compounding laws	White
September 22, 2014		Controlled Substances <i>Pre-work:</i> Review slides and read <u>Abood</u> Chapter 4	-List the schedules of controlled substances -State the basis of placing a drug in a schedule -Understand CS recordkeeping requirements	Gallagher
September 29, 2014		CS continued <i>Pre-work:</i> Review slides and read <u>Abood</u> Chapter 5	-Above continued -Describe Pseudoephedrine requirements	Gallagher
October 6, 2014		Additional Federal laws <i>Prework:</i> Review slides (Readings have already been completed)	-Understand a variety of other national laws governing the practice of pharmacy	Gallagher
October 13, 2014		WV law	-Understand WV statutes and regulations involved in pharmacy practice	White
October 20, 2014*		Midterm Exam		
October 27, 2014		WV law continued	-Above continued	White
November 3, 2014		Rules of Professional Conduct <i>Pre-work:</i> Review slides and see below for readings**		Farrell
November 10, 2014		Pharmacist Code of Ethics <i>Pre-work:</i> Review slides and see below for readings**		Farrell
November 17, 2014		Civil liability and contracts <i>Prework:</i> Review slides and read <u>Abood</u> pp 17-28, 393-	-Describe various civil legal precepts relevant to pharmacy practice	Gallagher

		<b>404</b>		
<b>November 24, 2014</b>	<b>No class</b>	<b>Thanksgiving Break</b>		
<b>December 1, 2014</b>		<b>Special federal laws and comparison of state laws</b>	<b>-Understand the concept of Duty to Warn and how it applies to pharmacy -Articulate the Learned Intermediary Doctrine -Compare and contrast certain state laws</b>	<b>White</b>
<b>December 8, 2014*</b>		<b>Final Exam</b>		

**\* - Indicates Major Exam / Assessment**

**\*\* Prework readings for the two Ethics sessions:**

1. Abood, pp.318-19;
2. American Pharmacists Association Code of Ethics (<http://www.pharmacist.com/code-ethics>);
3. American Pharmacists Association Code of Ethics with Interpretations (<http://www.ashp.org/DocLibrary/BestPractices/EthicsEndCode.aspx>);
4. General Pharmaceutical Council Student Code of Conduct (<http://www.pharmacyregulation.org/education/pharmacist/student-code-conduct>);
5. American Society of Consultant Pharmacists Code of Ethics (<https://www.ascp.com/sites/default/files/ASCP-code-of-ethics.pdf>);
6. American Association of Pharmacy Technicians Code of Ethics (<http://www.anthem.edu/pharmacy-technician-school/ethics>);
7. West Virginia Code regarding the practice of pharmacy (<http://www.wvbop.com/law1.htm>);
8. Alabama Board of Pharmacy Disciplinary Opinions (<http://www.lawofcompoundingmedications.com/2013/06/alabama-board-of-pharmacy-disciplinary.html>); and
9. California Board of Pharmacy Department of Consumer Affairs –Instructions How to File a Complaint ([http://www.pharmacy.ca.gov/consumers/complaint\\_info.shtml](http://www.pharmacy.ca.gov/consumers/complaint_info.shtml)).

#### **Course Evaluation (assessment):**

■ <b>Outline</b>	<b>25 points</b>
■ <b>IRAT/GRAT</b>	<b>75 points</b>
■ <b>Midterm</b>	<b>100 points</b>
■ <b>Comprehensive final</b>	<b>150 points</b>

#### **Course Evaluation (grading):**

**Point or Percentage Distribution:** *At each class, students will be assigned a randomly selected identifier for class participation; classroom attendance is mandatory.*

**Letter grades distribution:** A = 89.50 to 100%  
B = 79.50 to less than 89.50%  
C = 69.50 to less than 79.50%  
F = Less than 69.50%

**Assignment and examination grades will be posted in Blackboard within 7 days unless otherwise stated.**

**Attendance policy:** *Each student is required to attend class. Attendance is mandatory at graded events. Only excused absences accepted – see university and school policies.*

## **UNIVERSITY POLICIES**

University policies regarding **Academic Dishonesty, Students with Disabilities, University Computing Services' Acceptable Use, Affirmative Action, and Sexual Harassment** can be found at <http://www.marshall.edu/wpmu/academic-affairs/policies/>.

## **School of Pharmacy Policies**

## **SOCIAL JUSTICE POLICY STATEMENT**

Marshall University is committed to bringing about mutual understanding and respect among all individuals and groups at the University. As part of Marshall University, School of Pharmacy has made a commitment to social justice. Therefore, no one will be discriminated against on the basis of race, gender, ethnicity, age, sexual orientation, religion, social class, or differing viewpoints. Each student will be viewed as a valuable member of this class and as the faculty for the course, I will strive to facilitate an atmosphere/learning environment where mutual understanding and respect are actualized.

## ACADEMIC, ETHICAL, AND PROFESSIONAL CONDUCT

Student expectations for academic, ethical, and professional conduct are defined within the school's [Ethical and Professional Conduct Policy](#) and the university's [Academic Dishonesty Policy](#).

### Second Chance and Remediation Policy

Second chance and remediation are mechanisms designed to assist students who have struggled within the classroom environment in demonstrating achievement of classroom and curricular learning outcomes. These processes are described in sections 200.001.003 (Second Chance) and 200.001.004 (Remediation) of the [Academic Standards for Grading, Progressions, Dismissal, and Re-admission Policy](#).

### Test Security Policy

In order to ensure the security of all examinations, the School of Pharmacy has adopted the following policies:

#### 1. Test Administration

##### A. Non-electronic testing

- a. Students may not access any electronic equipment during the exam that has not been provided by the faculty, including but not limited to calculators, cell phones, laptops and PDAs.

##### B. Electronic testing

- a. Only those resources (electronic or otherwise) approved by the instructor may be used or accessed during the testing session.
- b. Students enrolled within courses using electronic testing must download and install the [Respondus Lockdown Browser](#). The installation will require an installation code that must be acquired from Computing Services.

#### 2. Test Review

- A. Students will not be allowed to view any exam without direct supervision of course faculty or site facilitator
- B. Students must review tests within time specified by the course faculty.
- C. Limited numbers of students may be allowed to view the exam at one time depending on office size, space, and faculty preference.
- D. Students will be allowed to review the exam only one time, and time limits may be placed on review as specified by course faculty.
- E. NO notes can be taken by the student while reviewing the test, and students are not allowed to access any electronics while reviewing the tests. NO copies electronic or written!
- F. Individual student printouts for exams are to be retained by the faculty.
- G. Faculty have the right to place further restrictions on test review as deemed necessary.