

Department Name and Number _____

Recommended SCNS Course Identification			
Prefix ___ ___ ___	Level ___	Course Number ___ ___ ___	Lab Code ___
Full Course Title _____			
Transcript Title (please limit to 21 characters) _____			

Effective Term and Year _____	Rotating Topic <input type="checkbox"/> yes <input type="checkbox"/> no
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Amount of Credit ___	Contact Hour: Base ___ or Headcount ___	S/U Only <input type="checkbox"/> yes <input type="checkbox"/> no
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Repeatable Credit <input type="checkbox"/> yes <input type="checkbox"/> no	If yes, ___ total repeatable credit allowed
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Variable Credit <input type="checkbox"/> yes <input type="checkbox"/> no	If yes, ___ minimum and ___ maximum credits per semester
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Course Description (50 words or less)

Prerequisites	Co-requisites
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Degree Type (mark all that apply) <input type="checkbox"/> Baccalaureate <input type="checkbox"/> Graduate <input type="checkbox"/> Professional <input type="checkbox"/> Other _____

Category of Instruction <input type="checkbox"/> Introductory <input type="checkbox"/> Intermediate <input type="checkbox"/> Advanced

Rationale and place in curriculum

Department Contact	Name _____	Phone _____	Email _____
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College Contact	Name _____	Phone _____	Email _____
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All UCC1 forms and each UCC2 form that proposes a change in the course description or credit hours must include this checklist in addition to a complete syllabus. Check the box if the attached syllabus includes the indicated information.

Syllabus MUST contain the following information:

Instructor contact information (and TA if applicable)

Course objectives and/or goals

A weekly course schedule of topics and assignments

Required and recommended textbooks

Methods by which students will be evaluated and their grades determined

A statement related to class attendance, make-up exams and other work such as: "Requirements for class attendance and make-up exams, assignments, and other work in this course are consistent with university policies that can be found in the online catalog at:

<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>."

A statement related to accommodations for students with disabilities such as: "Students requesting classroom accommodation must first register with the Dean of Student Office. The Dean of Students Office will provide documentation to the student who must then provide this documentation to the instructor when requesting accommodation."

Information on current UF grading policies for assigning grade points. This may be achieved by including a link to the appropriate undergraduate catalog web page:

<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>

A statement informing students of the online course evaluation process such as: "Students are expected to provide feedback on the quality of instruction in this course based on 10 criteria. These evaluations are conducted online at <https://evaluations.ufl.edu>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu>.

It is recommended that syllabi contain the following information:

1. Critical dates for exams and other work
2. Class demeanor expected by the professor (e.g., tardiness, cell phone usage)
3. UF's honesty policy regarding cheating, plagiarism, etc. Suggested wording: UF students are bound by The Honor Pledge which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: "On my honor, I have neither given nor received unauthorized aid in doing this assignment." The Honor Code (<http://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/>) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obliged to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.
4. Phone number and contact site for university counseling services and mental health services: 392-1575, <http://www.counseling.ufl.edu/cwc/Default.aspx>
University Police Department: 392-1111 or 9-1-1 for emergencies.

The University's complete Syllabus Policy can be found at: http://www.aa.ufl.edu/Data/Sites/18/media/policies/syllabi_policy.pdf

PHA 5XXX: The Pendulum of Controlled Substances

2 Semester Credit Hours

Prereq: open to PharmD students only

Course Purpose:

This elective course will explore in detail emerging issues related to the regulation of controlled substances at the federal and state level. Topics covered will include prescription drug abuse, prescription drug monitoring programs, pharmacy/pharmacist liability, and federal and state administrative actions surrounding controlled substances. In addition to class lectures and discussions, students will participate in active learning exercises allowing them to become more familiar with policy development involving controlled substances.

Course Faculty and Office Hours

Instructor

W. Thomas Smith, Pharm.D., JD

Email: tsmith@cop.ufl.edu

Phone: 352.273.6264

Office Hours

By appointment. Please contact faculty by phone or email to set up a date and time to have a conference call.

Place and Time of Class Sessions

Monday evenings; June 16-Aug 1; 9:00-10:30pm eastern time.

How This Course Relates to the Learning Outcomes You Will Achieve in your Pharm.D. Program:

This course prepares the Pharm.D. student to accomplish the following abilities and the related Student Learning Outcomes (SLOs) upon graduation:

- Perform pharmacist responsibilities within the medication use system and relate to the larger health care systems to assure safe and quality patient care. (SLO 3.1, 3.3)
- Communicate effectively with patients, caregivers, peer pharmacists, other pharmacy staff, and other health professionals. (SLO 4.1)
- Demonstrate ethical behaviors and adhere to legal requirements in pharmacy practice. (SLO 7.2)
- Solve complex practice problems (both patient-specific and general practice) using an evidence-based approach, other aspects of good clinical science, and informatics. (SLO8.1-8.2)

Course Objectives

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

1. Discuss state v. federal authority in the regulation of controlled substances.
2. Recognize the role of the Drug Enforcement Administration (DEA) regarding controlled substances under the federal Controlled Substances Act (CSA).

3. Discuss the concepts of “legitimate medical purpose” and “usual course of professional practice.”
4. Describe the “chilling effect” of aggressive regulation on legitimate patient care.
5. Describe the closed system of controlled substance distribution.
6. Explain the regulatory classification system for controlled substances.
7. Explain how controlled substances are diverted from legitimate medical use to illicit use.
8. Describe current issues surrounding prescription drug abuse.
10. Identify legal considerations regarding medication disposal.
11. Discuss emerging issues surrounding Prescription Drug Monitoring Programs.
12. Describe potential liability concerns for pharmacies and pharmacists regarding controlled substances.

Course Structure & Outline

Course Structure.

Multiple self-directed learning activities are required (e.g., readings, web-based learning) and at scheduled intervals students are to attend on-line classes for interactive learning sessions (e.g., lectures, case discussion). In addition students will required to interact out-of-class (e.g., discussion board; group assignments).

Course Outline/Activities. Refer to Appendix A.

Textbooks

This course has no text. Online references and other required readings and materials will be posted.

Active Learning Requirements

Students will be required to participate in active learning activities during class and outside of class. During class will include questioning, class participation, class debates, and small groups. Outside of class will include discussion board, group work, and assignments.

Student Evaluation & Grading

Evaluation Methods

Class Assignment 1	25%
Class Assignment 2	25%
Class Participation	10%
Discussion Board	10%
Final	30%

Full credit for class participation requires five postings weekly on discussion board; two postings must be original threads, and three must be responsive postings in a thread started by someone else. A week begins at 12:01 am Eastern on Sundays and ends at 11:59 pm Eastern on Saturdays. Each of these postings should be relevant to the class and original to the student. In order to earn credit, all original threads must be posted by noon Eastern on Fridays in order to give students time to respond to the original threads. Full credit for class participation also requires attendance at every Adobe Connect

class, adequate preparation for class, and appropriate participation in class. Those who participate very actively on discussion board may participate a little less actively in class, and vice-versa.

A link to UF's Grading Policies can be found here:

<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>

Grading Scale

A	93-100	B	83-86	C	73-76	D	63-66
A-	90-92	B-	80-82	C-	70-72	D-	60-62
B+	87-89	C+	77-79	D+	67-69	E	<60

Class Attendance Policy

Requirements for class attendance and make-up exams, assignments, and other work are consistent with university policies that can be found at:

<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>

Assignment/Exam Policy

Faculty should be contacted with any concerns after grades are released in a timely manner.

Make-up Quiz/Exam Policy

Make-up assignments and exams will only be permitted in accordance with UF's attendance and make up policies outlined above or if approved by the instructor in advance.

Students with Disabilities

Students requesting classroom accommodation must first register with the Dean of Student Office. The Dean of Students Office will provide documentation to the student who must then provide this documentation to the instructor when requesting accommodation.

Online Course Evaluation

Students are expected to provide feedback on the quality of instruction in this course based on 10 criteria. These evaluations are conducted online at <https://evaluations.ufl.edu>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu>.

General College of Pharmacy Course Policies

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy

3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

Complaints

Should you have any complaints with your experience in this course please visit:

<http://www.distancelearning.ufl.edu/student-complaints> to submit a complaint.

Appendix A (Schedule of Course Activities/Topics)

Activity	Dates	Reading Assignments	Learning Responsibilities
Week I Introduction to the Rules of Controlled Substance Distribution; State v. Federal regulation	June 16 to 22	<p>DEA Pharmacist's Manual http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html or http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf</p> <p>DEA Links http://www.deadiversion.usdoj.gov/ http://www.deadiversion.usdoj.gov/21cfr/index.html (CSA and Regulations)</p> <p>DEA FAQ http://www.deadiversion.usdoj.gov/index.html</p> <p>Gonzales v. Raich http://voicesofamericanlaw.org/media/documents/Raich_edited.pdf or http://www.law.cornell.edu/supct/html/03-1454.ZO.html</p>	<p>- Discussion Board</p> <p>- Class on June 16</p>

		Oregon v. Gonzales http://www.law.cornell.edu/supct/pdf/04-623P.ZO	
Week II FDA Role and REMS	June 23 to 29	FDA Role In Prescription Drug Abuse http://www.fda.gov/newsevents/testimony/ucm112718.htm FDA REMS http://www.fda.gov/Drugs/DrugSafety/default.htm then click on “Postmarket Drug Safety Information for Patients and Providers”; REMS information under this section; also on http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm video presentation / webinar http://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm	- Discussion Board - Class on June 23, 26 - Assignment 1 due June 29 - Class Assignment 1
Week II Concerns regarding Prescription Drug Abuse and Drug Accumulation	June 30 to July 6	White house report / additional resources http://www.whitehouse.gov/ondcp/prescription-drug-abuse (link to 2011 Prescription Drug Abuse Prevention Plan) FDA Role In Prescription Drug Abuse http://www.fda.gov/newsevents/testimony/ucm112718.htm FDA REMS http://www.fda.gov/Drugs/DrugSafety/default.htm then click on “Postmarket Drug Safety Information for Patients and Providers”; REMS information under this section; also on http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm video presentation / webinar http://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm Medication disposal article (to be posted later)	- Discussion Board - Class on June 23
Week III Drug Disposal	June 30 to July 6	Same articles as prior week; in addition: DEA proposed rules / resources http://www.deadiversion.usdoj.gov/fed_regs/rules/2012/fr1221_8.htm http://www.deadiversion.usdoj.gov/drug_disposal/	- Discussion Board - Class on June 30
Week IV PDMPs	July 7 to 13	- PDMP resources http://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/pdmp_fact_sheet_4-8-11.pdf https://www.bja.gov/evaluation/program-substance-abuse/pdmp2.htm http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm http://www.pdmpexcellence.org/content/pdmp-effectiveness	- Discussion Board - Class on July 7 -Class Assignment II

Week V and VI DEA Actions	July 14 to 20 and July 21 to July 27	<ul style="list-style-type: none"> - Chilling effect (http://www.aahpm.org/uploads/files/2009summercover.pdf) - DEA enforcement actions / cases against doctors (http://www.deadiversion.usdoj.gov/crim_admin_actions/index.html) - NAPB consensus document; AMA / Pharmacist concerns - Changing of Schedules (Vicoden?) - DEA News (“What’s New”: http://www.deadiversion.usdoj.gov/) 	<ul style="list-style-type: none"> - Discussion Board - Class on July 14 - Class on July 21
Final Exam	July 28	Final to be posted during class time.	

*** (Additional readings may be posted during the course)