PHAR 726: Evidence Based Medicine II – Literature Evaluation
Winter, 2019
Tuesday and Thursday 2:00 – 3:20 pm in Weniger 116

Faculty Responsible for the Course:

David Engen, PharmD, BCGP (Course Coordinator)
Office Hours: Room 105
Tues 3:30 – 4:30 pm (drop in)
Thurs 3:30 – 4:30 pm (appt only)
engend@oregonstate.edu 503-945-7719

Jessina McGregor, Ph.D. Epidemiology
mcgregoj@ohsu.edu 503-494-4722

Jon Furuno, Ph.D. Epidemiology
furuno@ohsu.edu 503-418-0361

General Catalog Description, Course Credits, & Prerequisites:
PHAR 726 Drug Literature Evaluation is a 3 credit course intended as an introduction to understanding and evaluating published clinical research.

Prerequisites: Second-year standing in the Pharm.D. Program.

Course Specific Measurable Student Learning Outcomes (SLOs) & Linkage to Program Level Student Learning Outcomes:

1. Identify and describe the distinguishing features, limitations and most appropriate clinical research role of the primary study designs. (1.1.4; 3.6.6)

2. Demonstrate an understanding of how the principles of causation and basic study design features supports the "evidence hierarchy" of Evidence-Based Medicine. (1.1.4)

3. Demonstrate the ability to evaluate observational study design for the presence, direction, and magnitude of bias and confounding and interpret the impact on the study results. (1.1.4)

4. Demonstrate an understanding of the properties of variables (e.g. qualitative, quantitative, continuous, nominal, ordinal) and how these properties influence the choice of bio-statistical tests. (1.1.4)

5. Determine the appropriate measures of central tendency and variability for a data set. (1.1.4)

6. Demonstrate an understanding of central limit theorem, sampling, probability and statistical inference. (1.1.4)

7. Accurately define, calculate, evaluate and interpret risk and association measures (e.g. odds ratios, risk ratios, absolute risk reduction, relative risk reduction, and number need to treat) for clinical relevance and statistical significance. (1.1.4; 3.1.2)

8. Accurately assess and interpret p-values and confidence intervals for statistical significance; Type I error, Type II error, the influence of power and influence of multiplicity. (1.1.4)

9. Differentiate between approaches used to identify confounding, effect modifiers, and statistically significant associations. (1.1.4)

10. Accurately assess and interpret confidence intervals for statistical significance in various study designs (i.e. superiority, equivalence, non-equivalence, non-inferiority). (1.1.4)

11. Critically appraise RCT outcomes and results for clinical relevance. (1.1.4; 3.1.2)
12. Critically appraise a randomized controlled trial for bias and consider any bias effects on the interpretation of the results. (1.1.4)

13. Demonstrate the ability to accurately interpret and apply the results of a RCT considering what is known about the biases, risks, benefits, clinical context and study population characteristics. (1.1.4)

Student Requirements for Credit and Evaluation of Performance:

<table>
<thead>
<tr>
<th>Assignment/Method of Evaluation</th>
<th>Points</th>
<th>Course Student Learning Outcome(s) Addressed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reflection/Application/Preparation Activities</td>
<td>5</td>
<td>1, 2, 3, 7–13</td>
</tr>
<tr>
<td>Homework Quizzes (and Group Activities)</td>
<td>20</td>
<td>4 – 8</td>
</tr>
<tr>
<td>Mid-Term (In class exam)</td>
<td>50</td>
<td>1 – 10</td>
</tr>
<tr>
<td>Covers assigned reading, on-line presentations, class assignments &amp; lecture material from weeks 1 - 5</td>
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<tr>
<td>RCT Evaluation Part 1 - Evidence Table (group assignment)</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>RCT Evaluation Part 2 - Bias Assessment (group assignment)</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Final Review</td>
<td>5</td>
<td>4 – 8; 10 – 13</td>
</tr>
<tr>
<td>Final Exam: RCT Critical Appraisal (In class exam)</td>
<td>60*</td>
<td>4 – 8; 10 – 13</td>
</tr>
<tr>
<td>Covers concepts from assigned reading, class assignments &amp; lecture material</td>
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</table>

* Students must show competency in critically evaluating and interpreting a randomized controlled trial. Competence is demonstrated by a score of 70% (C-) or greater on the final exam. Students failing to demonstrate competency on the final exam will be given an incomplete (I/D) and must complete a second assignment over the spring break (due on the second week of Spring Term). Students failing to demonstrate competency on the second assignment will be given a D in 726, regardless of performance on other class assessments, assuming overall performance warrants a grade greater than F. Those demonstrating competence on the second assignment will receive a course grade based upon an average of the first and the second score on the final exam assessment.

No excuses policy:
Students unable to take an examination at the scheduled time must make every attempt to notify the course coordinator before the examination period (email or phone message will suffice in the case of incapacitating illness). In all other situations, prior permission must be obtained from the course coordinator—and may require written documentation. All students are expected to take all regularly scheduled examinations. Make up examinations will not be offered during the term.

Time limit on exam re-grading: Requests for exam re-grading or corrections must be made in writing within one week of the exam’s return. A full exam review will follow each request.

Professional integrity. All assignments are intended to be individual efforts, unless otherwise indicated in writing, and may be reviewed using software to detect plagiarism. Failure to properly cite information, verbatim inclusion of text from other sources, or substantive similarity to other student’s submissions will be considered a violation of academic integrity. Violation of academic integrity results in a zero on the assignment and student referral to the College of Pharmacy Academic and Professional Standards committee.
Electronic Communication and Learning Management/Tracking Systems:
Students are required to maintain an active email account that is either your ONID account or linked to your ONID account. If your ONID email is forwarded to a second address, please assure that the second address is active and capable of receiving email (e.g. it has not exceeded its maximum storage capacity). Students are responsible for all email communication delivered to student ONID email accounts through the course website.

Attendance Requirements:
Attendance is not required for lectures. However, in class exercises and homework quizzes must be completed on time to receive full credit.

Late or Missing Assignments/Examinations:
Students will be required to complete all assignments and turn them in to the instructor by the day and time stated in the course outline. The required due date and time for all assignments are stated in this syllabus.

Notify the course instructor via email if you are ill or have an emergency that will result in missing the due date for a class assignment. If at all possible this notification should occur before the assignment is due, but generally no later than 24 hours afterward. Work schedules, weddings, and travel plans are not acceptable reasons for missing an assignment.

Students that turn in assignments after they are due will have sanctions as follows; however, each instance will be considered on a case-by-case basis:

- Assignments submitted after the due date/time may lose up to 50% of their total value.
- Assignments submitted greater than 24 hours after the due date/time are not accepted without special permission from the course coordinator.

The course coordinator must approve absences for the exam prior to the scheduled exam. Permission will only be granted for medical and/or family emergencies. Requests must be made in written form and given to the course coordinator. If permission is granted by telephone at the last minute (e.g. due to severe illness), it is the student’s responsibility to confirm the request in writing as soon as possible. Written confirmation of illness by a physician may be required when you return to class. The OSU Student Health Service is available to all students who are ill.

All students are expected to take the regularly scheduled exam. Make up examinations will only be allowed for students excused from the regularly scheduled exam due to illness/family emergency.

Closures or Curtailments (Including Inclement Weather):
- OSU: See OSU Campus Alert Website: [http://oregonstate.edu/main/alerts](http://oregonstate.edu/main/alerts)
- OHSU: Call the OHSU Alert Line: 503 494-9021 (option 3 for students)
- For students in clinical rotations, OSU or OHSU closure does not necessarily impact your clinical rotations. Contact your faculty of record for process.
## Course Topics

<table>
<thead>
<tr>
<th>Lecturer/ Date</th>
<th>Focus/Objective</th>
<th>Pre-Reading</th>
<th>Graded Assessment/ Group Activities and RAPs due day of class unless otherwise noted</th>
<th>Pts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>First Week</td>
<td></td>
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</tbody>
</table>
| Engen Lecture 1 1/8 | Course introduction and EBM review  
SLO #2 | N/A | RAP 1 | 0.5 |
| Engen Lecture 2 1/10 | Study Design  
|                |                 |             | Second Week                                                                     |     |
| Engen Lecture 3 1/15 | Literature Appraisal Fundamentals – Study Validity  
SLO #12, 13 | Jean-Baptist du Prel, Bernd Röhrig, Maria Blettner Critical Appraisal of Scientific Articles Dtsch Arztebl Int 2009; 106(7): 100–5. DOI: 10.3238/arztebl.2009.0100 | RAP 3 | 0.5 |
| Engen Lecture 4 1/17 | Literature Appraisal Fundamentals – Clinical Relevance and Applicability  
| Third Week | McGregor 1/22 | Observational Study Designs | Pre-Reading:  
| | SLO #1,2 | | | In-Class Group Activity: Designing a Study | 2  
| | | | Preview On-Line Presentations:  
Part 1: Introduction and Learning Objectives  
Part 2: Causation and Association  
Part 3: Case Series, Cross-sectional, & Case-Control studies  
Part 4: Cohort Studies and Review | |  
| McGregor 1/24 | Measures of Burden, Risk, & Association | Pre-Reading:  
| | SLO #7 | | | In-Class Group Activity: Calculating Risk/Association measures | 2  
| | | | Preview On-Line Presentations:  
Part 1: Introduction and Learning Objectives  
Part 2: Measures of risk and burden  
Part 3: Risk-based measures of association  
Part 4: Odds-based measures of association and Review | |  
| Fourth Week | 1/29 | No Class – Sim Lab in Portland | |  
| McGregor 1/31 | Observational Study Confounding & Biases | Pre-Reading:  
| | SLO #3,7 | | | In-Class Group Activity: Identifying bias/effect modification and confounding | 2  
| | | | Preview On-Line Presentations:  
Part 1: Introduction and Learning Objectives  
Part 2: Validity  
Part 3: Confounding  
Part 4: Effect Modification  
Part 5: Bias | |  

Raw Text:

**Third Week**

| McGregor 1/22 | Observational Study Designs | Pre-Reading:  
| | SLO #1,2 | | | In-Class Group Activity: Designing a Study | 2  
| | | | Preview On-Line Presentations:  
Part 1: Introduction and Learning Objectives  
Part 2: Causation and Association  
Part 3: Case Series, Cross-sectional, & Case-Control studies  
Part 4: Cohort Studies and Review | |  
| McGregor 1/24 | Measures of Burden, Risk, & Association | Pre-Reading:  
| | SLO #7 | | | In-Class Group Activity: Calculating Risk/Association measures | 2  
| | | | Preview On-Line Presentations:  
Part 1: Introduction and Learning Objectives  
Part 2: Measures of risk and burden  
Part 3: Risk-based measures of association  
Part 4: Odds-based measures of association and Review | |  
| Fourth Week | 1/29 | No Class – Sim Lab in Portland | |  
| McGregor 1/31 | Observational Study Confounding & Biases | Pre-Reading:  
| | SLO #3,7 | | | In-Class Group Activity: Identifying bias/effect modification and confounding | 2  
| | | | Preview On-Line Presentations:  
Part 1: Introduction and Learning Objectives  
Part 2: Validity  
Part 3: Confounding  
Part 4: Effect Modification  
Part 5: Bias | |
### Fifth Week

| Furuno 2/5 | Bio-stats Review | Pre-Reading:  
|-----------|-----------------|--------------------------------------------------|

**Specialized statistical approaches**

Optional reading:  
|-----------|-------|--------------------------------------------------|

### Sixth Week

| Engen Lecture 5 2/12 | RCT Internal Validity: Selection Bias | SLO #12, 13  
|---------------------|-----------------------------------|--------------------------------------------------|

| Engen Lecture 6 2/14 | RCT Internal Validity: Performance Bias  
|---------------------|-----------------|-----------------------------------------------|----------------------------------------------------------------|

**Group Activity:**  
Selection and Performance Bias  
Due: 2/14 @ 2 pm  
5

### Seventh Week

<table>
<thead>
<tr>
<th>2/19</th>
<th>Mid-Term Exam</th>
<th>Covers all reading, on-line presentations, lectures and class exercises from weeks 1-5</th>
<th>In class exam</th>
<th>50</th>
</tr>
</thead>
</table>

| Engen Lecture 7 2/21 | RCT Internal Validity: Detection (Data Collection) and Attrition Bias  
|---------------------|-------------------------------------------------|--------------------------------------------------|

**Group Activity:**  
Detection and Attrition Bias  
Due: 2/21 @ 2 pm  
0.5
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Engen Lecture 8 2/26</td>
<td></td>
<td></td>
<td>RCT Evaluation Part 1 – Prepare Evidence Table (Due 3/8 @ 5 pm)</td>
<td>5</td>
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<tr>
<td>RCT Evaluation Part 1</td>
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<tr>
<td>Clinical Importance</td>
<td></td>
<td></td>
<td>Group Activity: Results Interpretation (Focus on only the PRIMARY OUTCOME)</td>
<td>2</td>
</tr>
<tr>
<td>Clinical Importance</td>
<td>SLO #11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence Grading</td>
<td>SLO #13</td>
<td></td>
<td>RCT Evaluation Part 2 Evidence Grading (group task) Due 3/8 @ 5 pm</td>
<td>5</td>
</tr>
<tr>
<td>Evidence Grading</td>
<td></td>
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</tr>
<tr>
<td>Clinical Importance</td>
<td>Types of Clinical Trials and Secondary Studies</td>
<td>SLO #10, 13</td>
<td></td>
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</tr>
<tr>
<td>Tenth Week</td>
<td>3/12</td>
<td>Course wrap up</td>
<td>Final Exam Review Assignment (Due 3/15 @ 5 pm)</td>
<td>5</td>
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<tr>
<td>3/12</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3/14</td>
<td>Q &amp; A</td>
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<tr>
<td>Finals Week</td>
<td>TBA</td>
<td>Final Exam</td>
<td>Final Exam – TBA RCT Critical Appraisal</td>
<td>60</td>
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<tr>
<td>TBA</td>
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</table>
Course Grading Standards:
Final course grades will be posted with the OSU registrar based on the official Grade Deadline Calendar (http://registrar.oregonstate.edu/faculty-grade-deadlines) and will be generally assigned as indicated below.

<table>
<thead>
<tr>
<th>Letter Grades</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>A</td>
<td>90-100</td>
</tr>
<tr>
<td>B+</td>
<td>86-89</td>
</tr>
<tr>
<td>B</td>
<td>80-85</td>
</tr>
<tr>
<td>C+</td>
<td>76-79</td>
</tr>
<tr>
<td>C</td>
<td>70-75</td>
</tr>
<tr>
<td>D</td>
<td>65-69</td>
</tr>
<tr>
<td>F</td>
<td>Below 65</td>
</tr>
</tbody>
</table>

The College of Pharmacy policy for incomplete course grades is more restrictive than OSU policy. Incomplete grades must be resolved prior to the third week of the following term or a non-passing grade will be submitted.

Written Quiz and Exam Expectations and Process:
Students unable to take a quiz or examination at the scheduled time must make every attempt to notify the course coordinator before the examination period. Email or phone message will suffice in the case of incapacitating illness. In all other situations, prior permission must be obtained from the course coordinator—and may require written documentation. All students are expected to take all regularly scheduled examinations. Make up examinations will/will not be offered during the term.

Questions or concerns about points or grading of an exam need to be submitted in writing, along with the exam, within one week of the date the exam was returned to the students. Submitting such a request allows the instructor to review the exam for any additional oversights that may have occurred. Below are the College of Pharmacy standard examination procedures.

- Sit every other seat. Instructors/proctors may arrange seating in crowded room.
- No hats or caps. Put your possessions away. Turn phones to silent. Zip backpacks. Scratch paper is not allowed.
- Using a #2 pencil, PRINT your name (registered name, not your nickname) and OSU ID# on the Scantron and the paper exam. FILL IN THE APPROPRIATE BUBBLES.
- DO NOT fill in the form number.
- DO NOT fill in the section number.
- Every question has a best answer. Mark the appropriate letter on the answer sheet.
- Do not ask questions during the exam. Write on the exam or in the margins if you want to explain something. Only notify instructors/proctors if there are inaccuracies on the exam (e.g. numbering).
- Leave the room after the exam. Do not stay outside the room as it causes distraction.
• Please take care of personal needs, including bathroom needs, before the exam starts. Tell the proctor if it’s an emergency.

Evaluation and Improvement of Course Quality and Teaching Effectiveness:
Course and faculty evaluations are an essential component of the College’s assessment activities as well as critical for the individual faculty evaluation processes. Student feedback is used to improve instructional and curriculum quality as well as provides a mechanism for students to bring other issues to light that occur in courses. Students have several opportunities to participate in continual quality improvement of courses and the program. Additionally, the College of Pharmacy Curriculum and Assessment committees have student representatives and students are encouraged to bring suggestions for improvement directly to members of these committees.

The College uses a two-prong end of term evaluation system: 1) Faculty Evaluation; and 2) Course Evaluation. The Faculty Evaluation consists of 12 items established by the Oregon State University Faculty Senate. The College cannot change those items and results are used to evaluate individual faculty members. Faculty evaluations open and close based on faculty teaching schedules. Responses to course and faculty evaluations are anonymous.

The second prong is a college-specific set of items that we have deemed to more helpful in evaluating courses. The process uses 5 standard items about the course such as organization and learning outcomes being understandable. The survey also asks you to indicate whether you believe the course outcomes were met. In general, course evaluations will be open 7 days prior to the end of the term and close 7 days after the official end of the term. Student will receive reminders during this window. The open-ended comments collected during the course evaluation are shared with the Course Coordinator, the Curriculum Committee, and the Director of Assessment & Faculty Development. These comments are not part of a faculty teaching evaluation.

Below is a summary of changes made to this course based on student feedback:
- Improved mix of individual and group assessments
- Minimized overlapping assignments

General Oregon State University and College of Pharmacy Policies:
Academic and Professional Standards
The College of Pharmacy professional program has defined additional academic and behavioral expectations and characteristics considered essential to a student pharmacist and pharmacist. Individuals who choose to become student pharmacists do so with the understanding that admission, progression and graduation are dependent upon their capacity to personally demonstrate essential characteristics defined by the College and profession of pharmacy, available at http://pharmacy.oregonstate.edu/current-student-resources.

Additionally, OSU Student Conduct & Community Standards (SCCS) are available online at http://studentlife.oregonstate.edu/code and define expectations of students at the University level. Information about Academic Misconduct, Reporting of Incidents, and additional information about these expectations can be found at https://studentlife.oregonstate.edu/studentconduct.

To report a Conduct Incident please contact College of Pharmacy Student Services or use the “Report a Conduct Incident” on the SCCS page referenced above.
Basic Needs
Any student who has difficulty affording or accessing sufficient food to eat every day, or who lacks a safe and stable place to live, and believes this may affect their performance in the course, is urged to contact their academic advisor or the Human Services Resource Center (HSRC) for support (hsrc@oregonstate.edu, 541-737-3747). The HSRC has a food pantry, a textbook lending program and other resources to help. Furthermore, please notify the professor if you are comfortable in doing so. This will enable them to provide any resources that they may possess.

Civility, Student Behavior, and Non-discrimination
The goal of Oregon State University is to provide students with the knowledge, skill and wisdom they need to contribute to society. Our rules are formulated to guarantee each student’s freedom to learn and to protect the fundamental rights of others. Behaviors that are disruptive to teaching and learning will not be tolerated and will be referred to the Student Conduct Program for disciplinary action.

Oregon State University prohibits discrimination on the basis of protected status in any of its policies, procedures, or practices. Protected statuses include age, color, disability, gender identity or expression, genetic information, marital status, national origin, race, religion, sex, sexual orientation, or veteran's status. People must treat each other with dignity and respect for scholarship to thrive. Behaviors that create a hostile, offensive or intimidating environment based on any protected status will be referred to the Affirmative Action Office. For any questions regarding civility or acceptable behavior, please reference the University’s mission and values statements and the College of Pharmacy’s Essential Characteristics of a Student Pharmacist at http://pharmacy.oregonstate.edu/current-student-resources.

Copyright Information
Every reasonable effort has been made to protect the copyright requirements of materials used in this course. Class participants are warned not to copy, audio, or videotape in violation of copyright laws. Journal articles will be kept on reserve at the library or online for student access. Copyright law does allow for making one personal copy of each article from the original article. This limit also applies to electronic sources.

Diversity in the College of Pharmacy
The College of Pharmacy strives to create an affirming climate for all students including underrepresented and marginalized individuals and groups. Diversity includes but is not limited to differences in age, ethnicity, national origin, gender, religion, socioeconomic background, veteran status, sexual orientation, and marginalized groups. We believe diversity is the synergy, connection, acceptance, and mutual learning fostered by the interaction of different human characteristics.

Religious Accommodation of Students
Oregon State University strives to respect all religious practices. If you have religious holidays that conflict with any of the requirements of this class, please contact the Course Coordinator immediately to make alternative arrangements.

The University will grant students’ reasonable requests for religious accommodations where doing so does not conflict with reasonably necessary University goals. For more information, please consult the Religious Accommodation of Students Policy linked below or contact the Office of Equity and Inclusion: https://eoa.oregonstate.edu/nondiscrimination-basis-religion
Students with Disabilities
Accommodations for students with disabilities are determined and approved by Disability Access Services (DAS). If you, as a student, believe you are eligible for accommodations but have not obtained approval, please contact DAS immediately at 541-737-4098 or at http://ds.oregonstate.edu. DAS notifies students and faculty members of approved academic accommodations and coordinates implementation of those accommodations. While not required, students and faculty members are encouraged to discuss details of the implementation of individual accommodations.

Student Guidelines for Course Materials
To protect privacy rights, intellectual property rights, and the quality of the teaching and learning experience, the College of Pharmacy has adopted the following policies and guidelines governing course materials. Course materials include presentation materials created by instructors or other students, materials distributed in support of class activities, course assessments, and audio or video recordings.

• Except as provided below, students shall not give, sell, publish, or otherwise distribute any materials, in any medium, of any course given at the OSU College of Pharmacy, without the written consent of the course instructor and the Dean of the College of Pharmacy.
• Students currently enrolled in a course may, with the prior permission of the course instructor or guest lecturer, make audio or video recordings of course content, for use in study or other non-commercial purposes. If students intend to record photographs, video, or audio that includes other students, they must also obtain prior permission from the included students.
• Students currently enrolled in a course may distribute recordings to other currently enrolled OSU College of Pharmacy students for use in study or other non-commercial purposes arising from participation in the course, but they must ensure that recordings are distributed only in private forums. Any online distribution or posting of such recordings must be made on a password-protected site, such as the student Wiki.
• If granted permission to use recordings or content from faculty or student presentations (e.g. slides, figures, charts) in their own presentations, papers, or other scholarly activities, students must cite the source of those recordings or content appropriately.

Students should exercise special caution when creating or distributing audio, video, or image recordings of patients. Students must not create or distribute recordings of patients without securing the permission of everyone identifiable in the recording and their course instructor or preceptor.

Syllabus Changes and Retention
This syllabus is not to be considered a contract between the student and the College of Pharmacy. It is recognized that changes may be made as the need arises. Students are responsible for keeping a copy of the course syllabus for their records.