

# PHARMACY— PHARMACEUTICAL OUTCOMES AND POLICY

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## PHA 5270 Health Care and Patient Safety 3 Credits

**Grading Scheme:** Letter Grade

Provides an overview of applicable federal, state, local, and health and safety laws relevant to the practice of health care risk management and patient safety.

## PHA 5271 Health Care Risk Management 3 Credits

**Grading Scheme:** Letter Grade

Introduction to the concept of risk management in health care settings, describing its development, role of the health care risk manager, and connection between risk management, quality improvement and corporate compliance.

## PHA 6186 Pharm Outcomes/Policy Found 1 3 Credits

**Grading Scheme:** Letter Grade

This course is part of a two-course series, designed to provide students with an overview of drug discovery, development, approval, marketing, regulation, and use in the United States. Course I focuses on drug discovery, clinical trials, and the FDA approval process.

**Prerequisite:** Status as a Graduate Student, PharmD student or Post Baccalaureate student.

## PHA 6187 Pharm Outcomes/Policy Found 2 3 Credits

**Grading Scheme:** Letter Grade

This course is part of a two-course series, designed to provide students with an overview of drug discovery, development, approval, marketing, regulation, and use in the United States. Course II focuses on drug marketing, use, and public policy.

**Prerequisite:** Status as a Graduate Student, PharmD student or Post Baccalaureate student.

## PHA 6211 Applied Pharmacy Benefit Design 3 Credits

**Grading Scheme:** Letter Grade

Students will apply principles learned in PHA 6276 to advance their understanding of the fundamentals of pharmacy benefit practice. Using real-world pharmacy benefit trend data, students will take a stepwise approach to examining various components of trend and understanding how those may be influenced by tools used in pharmacy benefit design and management, external market forces, and other factors.

**Prerequisite:** PHA 6276.

## PHA 6213 Advanced Case Studies in Managed Care Pharmacy 3 Credits

**Grading Scheme:** Letter Grade

This course probes deeply into the most complex problems facing managed care pharmacy. Students will complete case study assignments that illustrate a real and current challenge facing managed care pharmacy programs today. This process will simulate situations encountered by professionals working within managed care organizations, consultancies, and the biopharmaceutical industry.

**Prerequisite:** PHA 6276.

## PHA 6227 Institutional Pharmacy Leadership I 3 Credits

**Grading Scheme:** Letter Grade

Addresses leadership topics relevant to institutional pharmacy with an emphasis on case study analysis. Topics include leading people, leading the pharmacy enterprise, leading change and innovation, providing leadership in safety and quality, and information technology and systems.

## PHA 6228 Institutional Pharmacy Leadership II 3 Credits

**Grading Scheme:** Letter Grade

Addresses leadership topics relevant to institutional pharmacy with emphasis on case-study analysis. Topics include leadership in effective financial management, building presence with executive leadership, leading for results, and gaining leadership skills through self-development.

## PHA 6246 Medication Safety & Technology 3 Credits

**Grading Scheme:** Letter Grade

This course provides an overview of medication safety technology used in healthcare today, including barcode medication administration, computerized provider order entry, automated dispensing cabinets, infusion smart pumps, clinical decision support, robots and IV workflow technology. Discussions will surround the function and purpose of the technology, how it improves safety, how people circumvent the safety features, and real-world medication events that occurred while using the technology.

## PHA 6264 Pharmaceutical Health Technology Assessment 3 Credits

**Grading Scheme:** Letter Grade

This course covers the essentials of health technology assessment (HTA) as applied to pharmaceuticals. The purpose of HTA is to assess a pharmaceutical treatment's comparative benefits, costs, and value. Students will explore how to structure an evaluation question, systematically identify relevant clinical and economic evidence, and interpret the results of an HTA. Finally, students will learn how HTA is applied to pricing, reimbursement, and coverage decisions in the US and abroad.

**Prerequisite:** Permission of instructor.

## PHA 6265 Introduction to Pharmaceutical Outcomes and Policy I 3 Credits

**Grading Scheme:** Letter Grade

Introduces students to the breadth of research issues in Pharmaceutical Outcomes and Policy, including legal, educational, regulatory and financial aspects of medication use; patient and provider behavior in medication use; the structure of pharmaceutical supply chain; and patient safety and risk management.

## PHA 6268 Pharmacoepidemiology and Patient Safety 3 Credits

**Grading Scheme:** Letter Grade

Exposure to research methodologies in pharmacoepidemiology relevant to drug safety, drug effectiveness, and outcome assessment.

Emphasizing observational study designs, including patient follow-up studies, case-control and cohort designs.

## PHA 6269 Pharmaceutical Products and Public Policy 3 Credits

**Grading Scheme:** Letter Grade

Relationships among pharmaceutical manufacturers, institutions, managed care, professions, and the public. The government's role in assuring high quality pharmaceutical products and services. Quality controls managed by the public and by industry. Congressional oversight of medication development, production, and use.

## PHA 6273 Structure, Process, and Outcomes of Regulation 3 Credits

**Grading Scheme:** Letter Grade

Emphasizes the role of the legislative, executive and judicial branches of state and federal government in the establishment of standards for pharmacy practice and drug distribution. It also places special emphasis on the administrative rule making process. Additionally, the course focuses on the purpose of government agencies, the approach to standards setting by each type of agency, and the effects of regulation on public health.

**PHA 6274 Federal Regulations of Drugs and Pharmacy 3 Credits****Grading Scheme:** Letter Grade

The Federal Food, Drug and Cosmetic Act, regulations promulgated by the Food and Drug Administration, and judicial interpretations of controversies in this area. Federal regulation of drug research, new drug approval, drug marketing and drug distribution. The balance sought by the FDA and other federal agencies in the protection of the public from unsafe and/or ineffective drugs, without unnecessarily restricting access to therapies.

**PHA 6275 Federal Regulations of Controlled Substances 3 Credits****Grading Scheme:** Letter Grade

The Federal Controlled Substances Act, regulations promulgated by the Drug Enforcement Administration, and judicial interpretations of controversies in this area. The "closed-system" of controlled substance distribution created under federal law. Federal restrictions on the manufacture, distribution and use of drugs that are subject to abuse. Treatment programs for the disease of addiction.

**PHA 6276 Pharmacy Benefit Design & Management 3 Credits****Grading Scheme:** Letter Grade

An overview of managed care pharmacy, focusing on the structure and function of the prescription benefits management within health plans and PBMs and the role of pharmacists with a managed care pharmacy department.

**PHA 6277 Ethics in Drug Development Production and Use 3 Credits****Grading Scheme:** Letter Grade

Governments, health professionals, patients and research institutions look to the field of ethics for guidance on how decisions should be made in the treatment of patients and in research. A process for ethical decision making. Basic theories and principles of biomedical ethics, with emphasis on utilitarianism. Application of principles to subjects such as informed consent, abortion/contraception, physician-assisted dying, experimentation with human subjects, and confidentiality.

**PHA 6278 State Regulation of Drugs and Pharmacy 3 Credits****Grading Scheme:** Letter Grade

State, federal, and nongovernmental regulation of health care professions and practice sites. Regulatory responses to professional misconduct. Role of professional self-regulation. Consumerism and state regulation.

**PHA 6279 Pharmaceutical Outcomes and Policy Capstone 3 Credits, Max 3 Credits****Grading Scheme:** S/U

This graduate capstone course is the culminating learning experience in the Master of Pharmacy, Pharmaceutical Outcomes and Policy program. Students will recall information and synthesize what they have learned in prerequisite courses to apply pharmaceutical research to project the impact of pharmaceutical policies on outcomes. At the end of this course, students will be able to prepare an oral and written evidence based pharmaceutical policy brief that policymakers can use.

**PHA 6280 Medicare and Medicaid 3 Credits****Grading Scheme:** Letter Grade

Costs and financing of Medicare and Medicaid. Eligibility, program administration, benefits, and relationships between state and federal agencies.

**PHA 6283 Introduction to Pharmacoeconomics 3 Credits****Grading Scheme:** Letter Grade

Fundamental methods of pharmacoeconomic analysis. Focuses on the theory, methods, and application of technology assessment in health care. Applications will be drawn from a variety of health care settings, including pharmaceuticals.

**PHA 6286 Pharmaceutical Microeconomics 3 Credits****Grading Scheme:** Letter Grade

Introduction to basic microeconomic principles as they are applied to pharmaceuticals. Elucidation of the economic tools and the fundamental concepts of choice, opportunity costs, supply and demand, elasticity, utility maximizing behavior, competition, monopolies and oligopolies in the healthcare market.

**PHA 6287 Pharmaceutical Health Economics 3 Credits****Grading Scheme:** Letter Grade

Examines economic principles and issues of health care and pharmaceuticals in the United States. Topics examined include health care structure and financing, market failures, human capital, and producer and consumer behavior.

**PHA 6288 Critical Review of Research Methods 3 Credits****Grading Scheme:** Letter Grade

Research design and methodology utilized in clinical research with a focus on understanding each component of the research process, including how to formulate a research question, develop hypotheses, analyze instruments, collect relevant data, data analysis, and critically interpret the results, while preserving the ethical guidelines for human subject research.

**PHA 6289 Regulating Clinical Research 3 Credits****Grading Scheme:** Letter Grade

Introduces history and current regulatory environment of human subjects research as a background to regulatory frameworks and contemporary issues structuring the development of clinical medical research, including federal regulations of Departments of Health and Human Services and those of the Food and Drug Administration, as well as non-federal sources of regulation.

**PHA 6717 Measurement in Pharmaceutical Outcomes and Policy Research 3 Credits****Grading Scheme:** Letter Grade

This course covers measurement of health outcomes as ascertained from real-world data, including patient-reported outcomes and clinical and administrative databases. Additionally, we address strategies for identifying biases arising from misclassification of exposure, outcomes and confounders, as well as approaches to mitigate such biases, including missing data problems and time-related biases in measurement and study design.

**Prerequisite:** PHC 6053 or equivalent and PHA 6891 or equivalent.**PHA 6741 Writing for Pharmaceutical Outcomes and Policy 3 Credits****Grading Scheme:** Letter Grade

Communication entails control: crafting a message such that a reader understands what a writer intends. We will use the pharmacy literature to identify how texts are made for different audiences, then use the literature to write evidence-based prose. The ultimate goal of the class is to develop (or polish) a suite of literacy skills useful for professional communication.

**PHA 6791 Systematic Reviews and Meta-Analyses for Pharmaceutical Interventions 3 Credits****Grading Scheme:** Letter Grade

The purpose of this course is to enable students to be able to participate in and complete systematic reviews for pharmaceutical interventions and to complete meta-analyses. Students will learn how to build a team, formulate research questions and hypotheses, develop search strategies, and abstract, collect and report data. Students who complete this course will understand the importance of systematic reviews in making clinical and policy decisions in health care.

**Prerequisite:** PHA 6793 (or its equivalent) and prior graduate-level statistics coursework or undergraduate level applied statistics. Students without prior statistics courses may be required to take PHA 6935 Quantitative Methods in Evidence-Based Pharmacy.

**PHA 6793 Evidentiary Basis of Pharmaceutical Use 3 Credits****Grading Scheme:** Letter Grade

The overall goal of the course is to familiarize students with methods and tools to evaluate the medical literature. Students will be exposed to an array of study designs and analytic methods. In clinical cases, students evaluate strengths and weaknesses of the published literature and use evidence to support their recommendations about the appropriate use of pharmaceuticals.

**PHA 6795 Quantitative Methods in Evidence-Based Pharmacy 3 Credits****Grading Scheme:** Letter Grade

This course introduces a range of quantitative methods used in the pharmacy and medical literature. The course topics include study designs, hypothesis testing, sampling, between group comparisons, correlations, regressions, and more. In this course, students develop the ability to critically evaluate methods used in quantitative research; thus, enabling students to apply evidence to the practice of pharmaceutical outcomes and policy.

**PHA 6796 Study Design in Pharmaceutical Outcomes & Policy Research 3 Credits****Grading Scheme:** Letter Grade

Methods for evaluation and improvement of drug therapy outcomes including critical appraisal of drug and clinical service literature with special focus on patient and medication safety.

**PHA 6797 Applied Pharmaceutical Research Communications 3 Credits****Grading Scheme:** Letter Grade

This course will describe the concept of pharmaceutical value from the viewpoint of the health care provider, the consumer, and the payer. Students will learn about various types of medical research communications for each audience and their applicable rules and regulations. This is an applied class where students will produce portions of a variety of medical research communications, culminating in a portfolio of work suitable for sharing in a job interview.

**PHA 6799 Medication Safety & Quality Program Evaluation 3 Credits****Grading Scheme:** Letter Grade

Explores the methodologies through which patient safety data are collected and evaluated. The use of existing databases on patient safety will be examined. The course includes design of a patient safety study, the evaluation of data, and the use of results from program evaluation to implement improvements to ongoing programs.

**PHA 6805 Applied Data Interpretation and Reporting of Findings in Pharmacy 3 Credits****Grading Scheme:** Letter Grade

Develops research skills including generation of questions; hypotheses testing; and testing, interpretation, and reporting of findings.

**PHA 6806 Pharmacoeconomic Modeling 3 Credits****Grading Scheme:** Letter Grade

Providing an introduction to methods and techniques for conducting pharmacoeconomic studies, including classifying disease, identifying pharmaceutical products from prescription claims, risk adjustment, practical decision analysis, Markov modeling, and indirect treatment comparisons.

**Prerequisite:** PHA 6283**PHA 6891 Introduction to Pharmacoepidemiology 3 Credits****Grading Scheme:** Letter Grade

Explores basic epidemiology principles with a particular focus on how they are applied to pharmaceuticals. Provides a basic understanding of causation, measure disease occurrence and causal effect, biases in study design, data analysis and use of epidemiology in clinical settings.

**PHA 6892 Practices and Procedures of the IRB 3 Credits****Grading Scheme:** Letter Grade

Describes the nuts and bolts of how Institutional Review Boards operate. Topics discussed include IRB membership, IRB authority, criteria for IRB approval of research or exemption from review, and suspension or termination of IRB approved research. The process of risk/benefit decision making is reviewed. The constituencies served by the IRB are examined. Current issues in IRB practice are discussed. Practical information about the week-to-week management of an IRB is explained.

**PHA 6893 Research Ethics 3 Credits****Grading Scheme:** Letter Grade

Introduce the student to the ethical issues that must be addressed in clinical research with human subjects. It will include an introduction to the primary theories and methods of ethical reflection and analysis, the conceptual distinctions and continuities between ethical and legal / policy questions, and illustrate the background to current issues with selected cases from the history of human subjects research.

**PHA 6910 Supervised Research 1-5 Credits, Max 5 Credits****Grading Scheme:** S/U

Supervised Research

**PHA 6935 Selected Topics in Pharmacy 1-4 Credits, Max 12 Credits****Grading Scheme:** Letter Grade

Open to all departments in the College of Pharmacy.

**PHA 6936 Advanced Topics in Pharmaceutical Sciences 1-2 Credits, Max 4 Credits****Grading Scheme:** Letter Grade

Written and oral presentation of research designs, protocols, papers, and critical appraisals with discussion and critical review of such topics.

**PHA 6937 Topics in Pharmaceutical Administration 2 Credits****Grading Scheme:** Letter Grade

Analysis of special topics and recent developments in pharmaceutical administration, including innovations in the distribution of drugs and health-care services.

**PHA 6938 Research Seminar 1 Credit, Max 3 Credits****Grading Scheme:** Letter Grade

Seminar required of graduate students in the College of Pharmacy.

**PHA 6940 Supervised Teaching 1-5 Credits, Max 5 Credits****Grading Scheme:** S/U

Supervised Teaching

**PHA 6971 Research for Master's Thesis 1-15 Credits****Grading Scheme:** S/U

Research for Master's Thesis

**PHA 7807 Advanced Pharmacoepidemiology 3 Credits**

**Grading Scheme:** Letter Grade

Structured as an interactive discussion of selected readings based on topics in contemporary pharmacoepidemiology and the application of advanced pharmacoepidemiology techniques.

**Prerequisite:** STA 6166 and STA 6167 and PHA 6717 and PHA 6805 and PHA 6268, or equivalents.

**PHA 7979 Advanced Research 1-12 Credits**

**Grading Scheme:** S/U

Research for doctoral students before admission to candidacy. Designed for students with a master's degree in the field of study or for students who have been accepted for a doctoral program. Not appropriate for students who have been admitted to candidacy.

**PHA 7980 Research for Doctoral Dissertation 1-15 Credits**

**Grading Scheme:** S/U

Research for Doctoral Dissertation