

Master of Science in Pharmacy

Major in Pharmacy Regulation & Policy

Acquire the Knowledge & Credentials For:

- Legal Compliance Officer
- Regulatory Affairs Specialist
- Government Relations Representative
- Other Rewarding Regulation & Policy Careers

UF | College of Pharmacy
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The University of Florida offers a part-time online major in Pharmacy Regulation and Policy (PRP) within the Master of Science in Pharmacy program. This major provides students with the opportunity to better understand the law and speak more authoritatively in the workplace when issues of law and regulation arise. Courses in the program are taught by national content experts. Courses are taught using a distance-learning format, thus students do not need to relocate to earn this degree.

Background: The PRP major was developed as a response to student demand based on a survey of University of Florida students and graduates. These prospective students aspire to regulatory and policy careers within pharmacy corporations, government agencies, professional associations, managed care organizations, and the pharmaceutical industry. The positions they will occupy include legal compliance, government relations, and regulatory affairs. The program takes two years for students to complete. All online courses are 7 weeks in length and are taken sequentially; two courses per semester. Online courses use Electronic Learning System (a University of Florida adaptation of WebCT Vista) as the learning platform and Elluminate for live online classes. Individual courses are available to those who wish to acquire limited specialized knowledge without making a commitment to the complete program. All students must attend three weekend seminars in Gainesville during the course of their two years of study.

Program Goals: Too often government regulations and policies stand in the way of effective drug treatments, and patients suffer as a result. There are also situations in which the people who provide pharmaceutical products and services fail to appreciate the significance of regulations and policies that affect those services and products, consequently the providers are put at a disadvantage. The purpose of the PRP program is to create a cadre of dedicated professionals who understand the regulatory and policy context of medications use and who can use their understanding of the process to advocate for regulatory and policy changes that promote good outcomes from drug therapy. Regulation and policy can be positive tools in the improvement of patient care, and those who understand how to mold regulation and policy can add tremendous value to patient care. The PRP masters program provides its students with the expertise and the credentials to serve that influential role.

The director of the Master of Science in Pharmacy Major in Clinical Research Regulation and Ethics is David B. Brushwood, an attorney and pharmacist, who is Professor of Pharmacy Health Care Administration at the University of Florida College of Pharmacy. Professor Brushwood has twice been selected as a Mayday Scholar by the American Society of Law, Medicine and Ethics. He was in Investigator on the Florida Partnership for End-of-Life Care project with colleagues at the College of Medicine. He has received grant funding from the Institute for the Advancement of Community Pharmacy, the National Institutes of Health, the Borchard Foundation and the National Association of Boards of Pharmacy. He has authored three books and over 200 scholarly publications.

Pharmacy Regulation & Policy Curriculum:

(3 credit courses unless indicated otherwise)

- The Structure, Process & Outcomes of Regulation
- Federal Regulation of Drugs & Pharmacy
- Federal Regulation of Controlled Substances
- Ethics in Drug Production, Distribution & Use
- Regulating Pharmaceutical Access & Cost
- State Regulation of Drugs & Pharmacy
- Medicare & Medicaid
- Pharmaceutical Products & Public Policy
- Practices & Procedures of Administrative Agencies
- Pharmaceutical Outcomes & Policy Seminar (3 times for 1 credit each time)

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Courses in the Curriculum

The Structure, Process and Outcomes of Regulation

This course describes the basis of government regulatory authority, including state and federal administrative agencies, state legislatures and the United States Congress, and the role of the courts in interpreting and applying laws. The focus of the course in on the connection between outcomes of patient care and the structures and processes that are required by regulation of those who provide care to patients. The content of the course emphasizes the pharmaceutical product and medical devices, reviewing cases in which harm has been done to patients from these products, and considering how appropriate regulation could prevent this harm without adversely affecting patient care.

Federal Regulation of Drugs and Pharmacy

This course reviews federal Food and Drug Administration theory and practice, with a particular emphasis on product labeling requirements and the new drug approval process. The course reviews the requirements for preclinical studies, the three phases of clinical investigation, and the conduct of postmarketing surveillance. IND and IDE requirements are studies. The "substantial evidence" necessary to support approval of a NDA, ANDA and SNDA are explored.

Federal Regulation of Controlled Substances

This course reviews the Federal Controlled Substances Act, regulations promulgated by the federal Drug Enforcement Administration, and judicial interpretations of controversies in this area. The "closed-system" of controlled substance distribution created under federal law is described. Federal restrictions on the manufacture, distribution and use of drugs that are subject to abuse are reviewed. The course also studies the treatment programs that are legally available to patients with the disease of addiction.

Regulating Drug Production, Distribution and Use

Regulations that expand or restrict access to pharmaceuticals and that increase or decrease costs are reviewed in this course. The course also reviews the obligation to provide care as well as state and federal regulation of private health insurance and managed care. The implications of EMTALA, ERISA, HIPAA and COBRA are discussed. There is an introduction to Medicare and Medicaid. The course also reviews technology assessment, drug pricing, and price controls.

Ethics of Drug Production, Distribution and Use

This is an introduction to biomedical ethics primarily as applied to pharmaceutical and medical device products. Subject areas include the provider-patient relationship, clinical research ethics, distribution of scarce resources, ethics and industry, and beginning and end of life issues. Topics of special interest are tissue engineering and stem cells, human cloning, xenotransplantation, defining diseases, genetic testing, and genomically customized medications.

Medicare and Medicaid

The relatively short history of federal regulation of research is discussed in this class. The "common rule" comprised of sections of federal regulations relating to human subjects research is thoroughly studied, including the distinction between research and innovative therapy, the requirement for informed consent, and the avoidance of conflict of interest. Research regulation by litigation is also studied through a review of legal cases that have applied federal criteria for clinical research. The process for developing risk management strategies for the appropriate supervision of research is reviewed.

State Regulation of Drugs and Pharmacy

Studies licensure and standards setting of health care professionals and professional practice sites. Reviews the mechanism for determination of initial and continuing competence of practitioners. Discusses regulatory responses to professional misconduct and the role of self-regulation. Reviews federal initiatives to regulate healthcare professionals and practice sites. Discusses the role of non-governmental organizations in the regulation of the health care professions. A review of consumerism and state regulation.

Pharmaceutical Products and Public Policy

In this course, students are challenged to consider the broader context of the research activities in which they will engage. Channels of distribution for pharmaceutical and medical device products are reviewed. The importance of intellectual property protection is discussed. The concept of comparative effectiveness is introduced. Pharmaceutical industry promotional practices, and the effect of them on research and clinical care, are examined. The global implications of domestic pharmaceutical policies are considered.

Practices and Procedures of Administrative Agencies.

This course describes the history of the FDA and CMS. Agency organization and responsibility is explained. Administrative practices and procedures are described, including formal and informal rulemaking. The course discusses the interaction of federal agencies with state regulators. It also discusses how to use regulation as a means to stimulate innovation. In this course, relationships between agencies and Congress, other agencies, providers and recipients of benefits are discussed. The course reviews how standards can be set through conditions of participation and the politics within the FDA and CMS.

Pharmaceutical Outcomes and Policy Seminar

This is a two-day exploration of a specific topic facilitated by an expert on the topic. Students are required to prepare for seminar by reading a book or a series of articles. Topics might be related to a drug safety, pricing, fraud and abuse, lobbying skills, or international trade in pharmaceuticals.

Schedule

Students who begin in Fall Semester (August)

Aug-Oct	Structure, Process, Outcomes of Regulation
Nov-Dec	Federal Regulation of Drugs & Pharmacy
Jan-Feb	Federal Regulation of Controlled Substances
Mar-Apr	Regulating Pharmaceutical Access & Cost
May-Jun	Ethics in Drug Production, Distribution & Use
Aug-Oct	State Regulation of Drugs & Pharmacy
Nov-Dec	Pharmaceutical Products & Public Policy
Jan-Feb	Medicare & Medicaid
Mar-Apr	Practices & Procedures of Administrative Agencies

Students who begin in Spring Semester (January)

Jan-Feb	Structure, Process, Outcomes of Regulation
Mar-Apr	Regulating Pharmaceutical Access & Cost
May-Jun	Ethics in Drug Production, Distribution & Use
Aug-Oct	Federal Regulation of Controlled Substances
Nov-Dec	Federal Regulation of Drugs & Pharmacy
Jan-Feb	Medicare & Medicaid
Mar-Apr	Practices & Procedures of Administrative Agencies
Aug-Oct	State Regulation of Drugs & Pharmacy
Nov-Dec	Pharmaceutical Products & Public Policy

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