# REGULATORY POLICY & HEALTH SYSTEMS

SPS Certificate website: https://sps.northwestern.edu/graduate-certificates/health-regulatory-policy-systems-compliance/

Drawing from courses in the Public Policy & Administration and Regulatory Compliance programs, this certificate combines the theory and practice of public policy with a specific focus on regulatory policy from the perspectives of both those who must develop and implement policies and those organizations and industries that must comply with them. The public policy courses provide an overview of the many facets of the U.S. regulatory policy environment, while the regulatory compliance courses address the specific legal, ethical, and operational issues that the health and life sciences fields must contend with in complying with regulations meant to protect patients and consumers.

## Certificate Offered

- Regulatory Policy and Health Systems, Graduate Certificate (https://catalogs.northwestern.edu/sps/certificates/graduate/regulatory-policy-health-systems/regulatory-policy-health-systems-graduate-certificate/)

## Regulatory Policy & Health Systems Courses

**HC_COM 410-DL Healthcare Regulatory Environment (1 Unit)**
This course facilitates an in-depth exploration of the healthcare laws, regulations, statutes, policy guidance and enforcement initiatives that serve as a framework for healthcare compliance. Topics include but are not limited to legal and ethical issues, patient safety, patient privacy and security, coding and billing, conflict of interest, anti-kickback, and False Claims.

**HC_COM 411-DL Healthcare Programs and Enforcement (1 Unit)**
This course provides a comprehensive overview of health care compliance programs, including each of the seven core elements and strategies for developing, implementing and managing effective compliance programs in a heavily regulated environment. The course describes compliance healthcare enforcement authorities, such as Medicare and Medicaid auditors (e.g., Recovery Auditors, UPIC's) and current key healthcare fraud initiatives. Topics also include the basics of conducting risk assessments, audits and investigations. Previous title: Healthcare Compliance Programs.

**HC_COM 413-DL Healthcare Billing Models & Systems (1 Unit)**
This course provides a basic understanding of billing and payment structure for healthcare services in the U.S. and systems that promote compliance with federal and state laws, audits, and communications with government and other parties. See the MSRC website for more details.

**HC_COM 415-DL IT Systems Compliance (1 Unit)**
Provides a working knowledge of the compliance oversight of healthcare IT systems. Focus is on systems used in healthcare service provider settings. Topics include identification of legal and regulatory computer system requirements used in the industry; ensuring system specifications and configurations meet regulatory requirements; setting criteria of system documentation to ensure compliance to inspectors; ensuring cyber security risks are mitigated; addressing European Union Privacy Laws for international systems; and identifying special considerations for mobile devices. Students will have the ability to manage the compliance aspects of IT systems throughout the system lifecycle (acquisition, upgrades and retirement). Students learn how to build procedures to address any system violations.

**MSRC 401-DL Quality Systems (1 Unit)**
Introduction to essential quality systems and the domestic and global regulatory landscape governing regulated industries. Includes a review of the historical context for the creation of the organizations that protect public health, including the Department of Health and Human Services and the Food and Drug Administration. Discusses the pivotal role of quality in determining value chains and innovation; compliance with quality systems contained within the Code of Federal Regulations (GxP and DHHS regulations), Malcolm Baldrige National Quality Award, International Organization for Standards, Total Quality Management, and International Conference on Harmonization, FDA Quality System Inspection Technique, National Committee for Quality Assurance and The Joint Commission for Accreditation of Healthcare Systems.

**MSRC 405-DL Applied Research and Writing (1 Unit)**
This course provides a foundation for writing academic and technical papers, affording students the opportunity to recognize and address the strengths and weaknesses in their own critical thinking and writing skills. The course emphasizes logical argument development, structure, clarity of thinking, and effective use of documentation. Students learn to evaluate the strengths and limitations of various research methods and how to select the best method for a given task.

**MSRC 435-DL Risk and Decision Management (1 Unit)**
This course explores theories and practical applications of risk management, risk communication, decision management, and crisis management in life science industries. Topics include failure modes and effects analysis; fault-tree analysis; human factors analysis, and hazard analysis and critical control points. Students learn to anticipate and avoid risk and hazards and manage those that arise in a holistic manner.

**MSRC 481-DL Leadership in the Regulatory Environment (1 Unit)**
Topics include leading teams, communication strategies, and navigating the particular challenges of the regulatory environment.

**MSRC 498-DL Capstone (1 Unit)**
he capstone project course is the culmination of the MSRC program and demonstrates to faculty a student's mastery of the curriculum and core competencies in the regulatory field. Assignments are chosen by the instructor. Students are individually assessed and graded throughout duration of the ten week class. Students should retain all course material from previous classes in the program, including textbooks, to successfully complete assignments.
**Prerequisite:** 9 courses and a 3.0 GPA.

**MSRC 499-0 Independent Study (1 Unit)**
Independent study.

**MSRC 590-0 Thesis Research (1 Unit)**
Independent thesis research.