

THE HEALTH REGULATORY PROCESS
(LAW 6390 — Spring, 2013)
Prof. Mantel
Syllabus and Course Policies

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Office Hours: Monday 2:00-3:00 p.m. and by appointment

Course Description

Federal and State governments execute and enforce laws affecting almost every aspect of health care. This course explores how legal, policy, and political considerations influence legislative enactments and administrative agencies' regulatory policies in the health care arena. The first part of the course examines the policy and political reasons for government intervention at the state and federal levels and the regulatory tools used by government to achieve its health-related regulatory goals. The second unit explores the manner in which administrative agencies' implement health care statutes, with a focus on legal considerations that constrain agencies' discretion and how agencies employ cost-benefit analysis and scientific evidence and risk analysis. The third unit addresses health care enforcement and compliance issues, including an overview of the enforcement tools available to agencies, factors influencing agencies' exercise of their enforcement discretion, and approaches utilized by agencies other than enforcement actions that promote compliance with regulatory requirements. Finally, we will discuss the ways in which the political branches, namely Congress and the President, influence agencies' policymaking process.

Course Materials: Materials to be provided in hard copy or via the course website at <http://www.law.uh.edu/faculty/jmantel/health-regulatory-process.html>.

Course Policies:

Grading: The course grade will be based on four components: (1) class participation; (2) a 10-12 page essay applying the concepts covered in the first part of the course; (3) an exercise applying cost-benefit, scientific, and risk analysis principles; and (4) a 12-15 page final essay.

- (1) **Class Participation:** 15 percent of the course grade will be based on class participation. Please note that this is not a good class to take if you want to sit back and passively monitor the proceedings. Preparation and active participation will be expected. That said, I understand that illness or other situations may prevent you from being adequately prepared for class. If you are not prepared for class, I will give you a "pass" provided you ask me not to call on you prior to the start of class. You are allowed no more than two passes for the semester. If I call on you and you are unprepared, you will be required

to choose the classmate who must answer my question in your place. Pursuant to the Law Center's policy, you must attend at least 80% of all class meetings; however, you should strive to attend 100%. Missing more than 20% of classes will result in your being dropped from the course consistent with the law school's policies.

- (2) **Essay #1.** You will draft a 10-12 page essay applying one or more of the concepts covered in the first part of this course. I will provide you with a list of essay topics. More details regarding the memorandum's format, content, and due date will be discussed later in the semester. 25 percent of the course grade will be based on the essay.
- (3) **Exercise.** You will be asked to apply the principles we cover in the cost-benefit analysis and scientific evidence and risk analysis units to a hypothetical situation. Your analysis will be due approximately one week after we finish covering the scientific evidence and risk analysis unit. 25 percent of the course grade will be based on this exercise.
- (4) **Essay #2.** You will draft a 12-15 page essay discussing general themes covered throughout the course. More details regarding the final memorandum's format, content, and due date will be discussed later in the semester. 35 percent of the course grade will be based on the essay. This assignment is due on the last day of classes (i.e., Monday, April 30th). 35 percent of the course grade will be based on this assignment.

Seating Assignments: After the first week of class, I will create a seating chart. You must sit in your assigned seat for the remainder of the semester.

Cell Phones/Pagers: During class, all electronic devices should be set to silent mode.

Office Hours: I will hold office hours in my office on Mondays from 2:00-3:00 p.m. and by appointment. You may also email me questions. Please feel free to come by to see me not only about class matters, but for course selection guidance, career counseling, or any other matter related to your legal education and career.

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COURSE OUTLINE & READING LIST

UNIT 1: REGULATORY GOALS AND METHODS OF REGULATION

I. OVERVIEW OF FEDERAL AND STATE HEALTH AGENCIES

No assigned readings

II. JUSTIFICATIONS FOR THE REGULATORY STATE

A. The Limitations of Tort Law and the Markets

- Lisa Schultz Bressman et al, *THE REGULATORY STATE*, 59-61 (2010)
- Sidney Shapiro and Joseph Tomain, *REGULATORY LAW AND POLICY: CASES AND MATERIALS* 40-43, 49-62 (3d ed. 2003)

B. Application: Ensuring the Quality of Care

- Timothy Stoltzfus Jost, *The Necessary and Proper Role of Regulation to Assure the Quality of Health Care*, 25 *HOUS. L. REV.* 525 (1988) (excerpts)

C. Application: Health Insurance and Health Care Reform

- Bernadette Fernandez, CRS Report for Congress, *HEALTH INSURANCE: A PRIMER* (2005) (excerpts)
- The Patient Protection and Affordable Care Act, Pub. L. 111-148, § 1201 (specifically the amendments to §§ 2701, 2702, 2703, 2704, and 2705 of the Public Health Services Act); §§ 1401 and 1501

III. REGULATION AND POLITICS – AN INTRODUCTION

A. Public Choice Theory and the Problem of Collective Action

- Sidney Shapiro and Joseph Tomain, *REGULATORY LAW AND POLICY: CASES AND MATERIALS*, 78-87 (3d ed. 2003) (includes excerpts from Michael Levine, *Revisionism Revised: Airline Deregulation and the Public Interest*, 44 *LAW AND CONTEMPORARY PROBLEMS* 179, 180-85 (1981) and James Q Wilson, *The Politics of Regulation*, in *THE POLITICS OF REGULATION* 367-72 (J. Wilson ed. 1980))

B. Application: The Politics of the Medicare Prescription Drug Benefit

- Jonathan Oberlander, *Medicare and the Politics of Prescription Drug Pricing*, 64(6) *N.C. MED. J.* 303 (2003)

IV. FEDERALISM ISSUES

A. Rationales Supporting State vs. Federal Action

- Bovberg, et al., *State and Federal Roles in Health Care: Rationales for Allocating Responsibilities*, in *FEDERALISM AND HEALTH POLICY* 25-57 (Holhan, et al. ed, 2003)

B. Application: Health Care Exchanges

- Reed Abelson, *Proposals Clash on States' Role in Health Plans*, N.Y. TIMES B1 (January 14, 2010)

V. REGULATORY TOOLS

A. Framework for Evaluating Regulatory Tools

- Lester M. Salamon, *The New Governance and the Tools of Public Action: An Introduction*, 28 FORDHAM URB. L.J. 1611 (2000) (excerpt)

B. Standard-Setting Regulations – Quality Standards for Nursing Homes

- Richard B. Stewart, *Beyond Delegation Doctrine*, 36 AM. U. L. REV. 323, 329-30 (1987)
- Alexander D. Eremia, *When Self-Regulation, Market Forces, and Private Legal Actions Fail: Appropriate Government Regulation and Oversight Is Necessary to Ensure Minimum Standards of Quality in Long-Term Health Care*, 11 ANNALS HEALTH L. 93 (2002) (excerpt)
- Marshall B. Kapp, *Quality of Care and Quality of Life in Nursing Facilities: What's Regulation Got To Do With It?*, 31 MCGEORGE L. REV. 707 (2000)

C. Financial Incentives – Pay For Performance

- Institute of Medicine, *REWARDING PROVIDER PERFORMANCE: ALIGNING INCENTIVES IN MEDICARE* (2007) (excerpts)
- Elliott S. Fisher, *Paying for Performance – Risks and Recommendations*, 355 NEW ENG. J. MED. 1845 (2006)

D. Provision of Information – Public Disclosure of Quality Information for Plans and Providers

- Timothy Stolfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 ARIZ. L. REV. 825 (1995)
- E.C. Schneider and T. Lieberman, *Publicly Disclosed Information About the Quality of Health Care: Response of the U.S. Public*, 10 QUAL. HEALTH CARE 96 (2001)

UNIT 2: STATUTORY IMPLEMENTATION BY AGENCIES

I. WHY DOES CONGRESS DELEGATE TO AGENCIES

II. LEGAL CONSIDERATIONS

A. Overview of the Administrative Procedure Act (APA)

B. Judicial Review: Deference to Agency Interpretations, The Arbitrary and Capricious Standard

C. Statutory Constraints on Agency Action

D. Legal Considerations: Logical Outgrowth Doctrine, Legislative Rules vs. Interpretive Rules

III. COST-BENEFIT ANALYSIS AND QALYs

A. Introduction

B. Valuing Life and Good Health

C. Final Thoughts

IV. SCIENTIFIC EVIDENCE AND RISK ANALYSIS

A. Introduction

B. Application – EPA Determination of Whether Formaldehyde is a Significant Risk

C. Application – FDA and Plan B

UNIT 3: ENFORCEMENT AND COMPLIANCE ISSUES

I. INTRODUCTION TO HEALTH CARE FRAUD AND ENFORCEMENT

II. PROMOTING COMPLIANCE

UNIT 4: CONTROL OF AGENCY ACTION BY THE POLITICAL BRANCHES

I. REASONS FOR OVERSIGHT

II. CONGRESSIONAL CONTROL OVER AGENCIES

A. Introduction

B. Application -- NIH Research Grants

III. PRESIDENTIAL CONTROL OVER AGENCIES