PHC 6102
Principles of Health Policy & Management

Policy Implementation: Rulemaking
Objectives

• Identify key features of the rulemaking process
• Distinguish between law and regulation in health policy
• Explain the roles of the different branches of government in rulemaking
• Understand the role of special interests in the process of rulemaking
• Recognize key federal regulatory agencies in U.S. healthcare
Overview

• Policy formulation
  1. Agenda setting
  2. Legislative development

• Policy implementation
  1. Rulemaking
  2. Operations

• Policy modification
Health Policy Making Process

Preferences of individuals, organizations, and interest groups, along with biological, cultural, demographic, ecological, economic, ethical, legal, psychological, social, and technological inputs

Policy Formulation Phase
- Agenda Setting
  - Problems
  - Possible Solutions
  - Political Circumstances
- Development of Legislation
- Window of Opportunity*

Policy Implementation Phase
- Bridged by Formal Enactment of Legislation
- Rulemaking
- Operation

Policy Modification Phase
- Feedback
- Feedback from individuals, organizations, and interest groups experiencing the consequences of policies, combined with the assessments of the performance and impact of policies by those who formulate and implement them, influences future policy formulation and implementation.

*The window of opportunity opens when there is a favorable confluence of problems, possible solutions, and political circumstances.

Rulemaking

• Regulations and rules are synonymous terms
• After enactment of legislation, responsibility shifts:
  – From the Legislative branch (Congress)
  – To the Executive branch (President)
• Regulations carry the force of law
• Subject to Congressional oversight
• Regulatory actions are subject to judicial review
Regulators

• Executive branch operates regulatory agencies
• Agencies are legally authorized to issue regulations
• Laws are rarely explicit, so delays are common
• Formal rules exist for rulemaking
Federal Regulators

• 15 federal executive departments

• Department of Health and Human Services
  – Food and Drug Administration (FDA), National Cancer Institute, National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Office of Inspector General (OIG)

• Centers for Medicare and Medicaid Services (CMS) promulgates regulations on Medicare and Medicaid
Notice of Proposed Rules

Public Comments and Final Rule

Role of Special Interests

• Critical interaction between regulatory agency and affected interest groups
  – Hospitals, managed care organizations, public health departments, physicians, nurses, durable medical equipment suppliers, and ordinary citizens
  – CMS received over 7,000 comments on Medicare Part D regulations outlining the rules of prescription drug coverage in Medicare

• An example from ObamaCare
  – Medical Loss Ratio
Rule Takes Effect

42 CFR D

Centers for Medicare & Medicaid Services, HHS

§ 401.102

(a) The regulations in this subpart:

(1) Implement section 1106(a) of the Social Security Act as it applies to the Centers for Medicare & Medicaid Services (CMS). The rules apply to information obtained by officers or employees of CMS in the course of administering title XVIII of the Social Security Act (Medicare), information obtained by Medicare intermediaries or carriers in the course of carrying out agreements under sections 1816 and 1842 of the Social Security Act, and any other information subject to section 1106(a) of the Social Security Act;

(2) Relate to the availability to the public, under 5 U.S.C. 552, of records of CMS and its components. They set out what records are available and how they may be obtained; and

(3) Supplement the regulations of the Department of Health and Human Services relating to availability of information under 5 U.S.C. 552, codified in 45 CFR part 5, and do not replace or restrict them.

(b) Except as authorized by the rules in this subpart, no information described in paragraph (a)(1) of this section shall be disclosed. The procedural rules in this subpart (§§ 401.106 through 401.152) shall be applied to requests for information which is subject to the rules for disclosure in this subpart.

(c) Requests for information which may not be disclosed according to the provisions of this subpart shall be denied under authority of section 1106(a) of the Social Security Act and this subpart, and furthermore, such requests which have been made pursuant to the Freedom of Information Act shall be denied under authority of an appropriate Freedom of Information Act exemption, 5 U.S.C. 552(b).

§ 401.102 Definitions.

For purposes of this subpart:

Act means the Social Security Act.

Freedom of Information Act rules means the substantive mandatory disclosure provisions of the Freedom of Information Act, 5 U.S.C. 552 (including the exemptions from mandatory disclosure, 5 U.S.C. 552(b), as implemented by the Department’s public information regulation, 45 CFR part 5, subpart F and by §§ 401.106 to 401.152 of this subpart.

Person means a person as defined in the Administrative Procedure Act, 5 U.S.C. 551(2). This includes State or local agencies, but does not include Federal agencies or State or Federal courts.

Record has the same meaning as that provided in 45 CFR 5.5.

Subject individual means an individual whose record is maintained by the Department in a system of records, as the terms “individual,” “record,” and “system of records” are defined in the Privacy Act of 1974, 5 U.S.C. 552a(a).

Source: U.S. Government Printing Office
Questions

1. Is there a difference between who creates laws and who creates regulations?
2. Who oversees regulatory actions?
3. What organization promulgates regulations regarding Medicare?
4. What is the role of interest groups in rulemaking?
5. How can interested parties influence the rulemaking process?