1. Hello and welcome to “Policy Implementation: Rulemaking.” Rulemaking is the first stage of Policy Formulation. The content for this lecture is taken, among other cited sources, from Public Health Administration by Lloyd F. Novick, et al., chapter 6, and Health Policymaking in the United States, by Beaufort B. Longest, chapter 5.

2. The objectives of this lecture are:
   - 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

3. In previous lectures, the stages of Policy Formulation were presented. Agenda Setting is established through a framing of health problems and creation possible solutions during a set certain political circumstances. Legislative Development is the point in the Policy Formulation phase where specific health policy proposals are turned into legislation. In this part of the series, we will review the first stage of the Policy Implementation phase – rulemaking. This lecture covers rulemaking at the federal level, but you should understand that the key points apply to state and local governments, as well.

4. As you can see in the chart developed by Dr. Longest, the Policy Implementation phase begins after the formal enactment of legislation into law. In the box on the right, rulemaking is the first stage of the implementation of enacted legislation. We will review the Policy Operation and Policy Modification stages in subsequent lectures.

5. Regulations and rules are synonymous in this context. After enactment of legislation, the responsibility shifts from the Legislative branch (Congress) to the Executive branch (President). Regulations carry the force of law. Most of these federal agencies are under the supervision and direction of the President. All are subject to oversight by Congress, and almost all of their regulatory actions are subject to judicial review.

6. The Executive branch operates the regulatory agencies. Rulemaking is necessary because legislation is rarely explicit enough for direct implementation of laws. The requirement for regulation details can vary from very broad to very specific. When the regulators are granted a great deal of discretion as to how that intent should be implemented, delays are common. There are formal rules for rulemaking that will be explained in detail later in this lecture.

7. So, who are federal regulators? You may be familiar with many of them. There are a total of 15 federal executive departments that are headed by a politically appointed secretary. Some of these include: Agriculture, Commerce, Defense, Education, Treasury, Homeland Security, Transportation, and Energy. Each of these secretaries is a part of the President’s formal team advisors, known as the Cabinet.

As an example, why don’t we look at the Department of Health and Human Services? The Department of Health and Human Services has numerous operating divisions, a few of which
may sound very familiar to you. Some include the Food and Drug Administration (FDA), National Cancer Institute, National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and Office of the Inspector General (OIG). Let me offer a note about this OIG. While each federal department has its own OIG, the HHS’ OIG is the largest inspector general's office in the federal government, with more than 1,700 employees dedicated to combating fraud, waste and abuse of HHS programs. A majority of OIG’s resources goes toward the oversight of Medicare and Medicaid programs that represent a significant part of the federal budget.

The Centers for Medicare and Medicaid Services (CMS) is also an operating division of the Department of Health and Human Services. CMS promulgates regulations on Medicare and Medicaid. So to clarify this rulemaking process, let me offer an example regarding how the Centers for Medicare and Medicaid implements policy. I will use a fictional example rooted in fact from the Affordable Care Act; based on a true story, if you will. Let’s say that Congress passes a law requiring CMS to improve the quality of health services provided at hospitals for Medicare beneficiaries. In this made-up example, the law simply states that the Secretary of the Department of Health and Human Services (meaning CMS) “shall institute a pilot program to improve inpatient health quality and reduce costs to the Medicare program.” This lacks details, of course, but the intention is clear – better quality, less cost. What happens next in the “Medicare Inpatient Quality Improvement Pilot” rulemaking process will be explained in the next slides.

8. A very important aspect of implementing laws through rulemaking is public involvement. Reviewing the flow chart developed by Copeland, the rulemaking process begins when Congress passes a law (also called a statute) that requires an agency to write regulations. So, from our example above, CMS must write rules that improve inpatient care for Medicare beneficiaries and reduce cost for the Medicare program.

The agency drafts regulations and circulates them internally for approval. Prior to publication, the proposed rules are sent to the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) to improve the management of information resources and reduce unnecessary paperwork burden. Then Notices of Proposed Rules for the “Medicare Inpatient Quality Improvement Pilot” would be published in a document called the Federal Register. The Federal Register provides public notice of the activities of the federal government, including Presidential documents, executive orders, proclamations, rules and regulations, proposed rules, notices, hearings, meetings, and administrative orders.

9. Following the publication of a Notice of Proposed Rules Federal Register, all interested parties may comment in writing, or, at the discretion of the agency, by oral presentations. Of course, the hospital lobby has many comments about the proposed rules in our fictional example. So do various quality measurement groups, such as Leap Frog and NCQA. These comments are reviewed internally, and the rules are amended, as necessary.

10. Special interests have a tremendous role in the implementation of policy, and the rulemaking phase in particular. The interaction between a regulatory agency and affected interest group can be formal, as in commenting on rules, and informal, such as one-on-one meetings with regulators. Examples of entities affected by health regulations are hospitals, managed care organizations, public health departments, physicians, nurses, durable medical equipment suppliers, and ordinary citizens. An example of the intensity of special interest involvement in the rulemaking process is when CMS received over 7,000 comments on Medicare Part D regulations outlining the rules of prescription drug coverage in Medicare.
As an example from the Affordable Care Act, also called health care reform or ObamaCare, lobbyists were successful in getting regulations relaxed. The law that required health insurers to pay a minimum amount of patients’ insurance premium on direct health care costs. The law intended to limit the amount an insurer could spend in sales and marketing and keep in profits. This is called the Medical Loss Ratio provision, but the details here are not important for you to know. It is important to understand, however, that special interests were able to influence the MLR policy by expanding what regulators would consider as “direct healthcare costs.” As a result of lobbying by large insurers and the health insurance trade group, costs associated with costs incurred by health insurers that are intended to improve health care quality are considered “direct healthcare costs.” Unfortunately, many consider these “quality programs” as cost cutting activities in disguise. That’s debatable, but the influence that special interests have over the rulemaking process can be agreed to by all.

11. When the consideration of the public comment is completed by the regulator, final rules are promulgated by a federal agency and published in the Federal Register. Ultimately these rules and regulations are reorganized by topic or subject matter and “codified” in the Code of Federal Regulations (CFR). As discussed above, Congress and the courts may challenge these regulations oversight and budget appropriations functions.

12. Here is an example of Code of Federal Regulations (CFR) promulgated by CMS. In our fictional example regarding “Medicare Inpatient Quality Improvement Pilot,” the rules would state exactly how quality would be measured, how the data should be reported, how payments would be reduced if the hospitals did not meet the quality measure targets, etc.

13. This concludes the lecture on “Policy Implementation: Rulemaking.” The following questions are some that you will be expected to know:

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?

Thank for your attention. Please go to the next lecture in the series, “Policy Formulation: Policy Operation.”