Regulatory Agencies Involved with the Clinical Laboratory

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ABBREVIATIONS: APA = Administrative Procedures Act; APC = ambulatory payment classifications; CBER = Center for Biological Evaluation and Research; CDC = Centers for Disease Control and Prevention; CMS = Centers for Medicare and Medicaid Services; CLIA '88 = Clinical Laboratory Improvement Amendments of 1988; CFR = Code of Federal Regulations; DRG = diagnosis-related groups; FACA = Federal Advisory Committee Act; FDA = Food and Drug Administration; HHS = Department of Health and Human Services; OIVD = Office of In Vitro Diagnostics Device Evaluation

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Passing legislation in Congress is only the beginning of lawmaking. Crafting of rules and regulations turns ideas into actual, enforceable laws. Rules and regulations can be thought of as the operator's manual for laws and have the full force of law. Two laws, the Administrative Procedures Act (APA) and the Negotiated Rulemaking Act ("neg reg") control the writing of rules and regulations.[1]

The APA defines rules and regulations as statements from federal agencies that "regulate the future conduct of either groups of persons or a single person" and "implement, interpret or prescribe law or policy".[2] They are written by executive branch agency staff, not by members of Congress. The Negotiated Rulemaking Act of 1990 describes a voluntary process that brings interested parties and government together to negotiate the language of a regulation. The committee is chartered under the Federal Advisory Committee Act (FACA) and consists of representatives from groups that will be affected by the regulation such as the public sector, public interest groups, industry and practitioners, or individuals.

THE EXECUTIVE BRANCH

The structure of the federal government in the United States is divided into the executive branch, legislative branch, and judicial branch. Each is autonomous and has agencies and commissions that deal with the day-to-day business of government.

The agencies of the executive branch are in departments created with the consent of Congress (Table 1).[3] Each department is administered by a secretary who serves at the designation of the President and must be approved by Congress.[4] Each department is further subdivided into agencies and branches, headed by administrators who are political appointees. That means that the agenda of any agency, what it hopes to accomplish or how it will approach its mission, often changes with the politics of the president. Congress can also bring pressure to bear on an executive department by enacting or amending laws that direct the department or one of its agencies. Since none of the employees in federal agencies are elected, this level of political influence can come as a surprise to anyone who has an interest in the work or scope of authority of a particular agency. This also means that the way new regulations are written and the approach to enforcement of existing regulations can vary dramatically from administration to administration, effectively changing the impact of any law.

For instance, between the time that the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) was enacted and the regulations were written, there was a national election. The initial outrage about poor laboratory practices, harm inflicted on individuals because of erroneous laboratory results, the questionable validity of cholesterol results, and the accuracy of Pap smears had dissipated. The new president, new Congress, and new secretary of Health and

Human Services didn't share the same passion for reform as the original sponsors of the bill. Physician groups, hospital associations, and representatives of other healthcare providers who wanted to do laboratory testing lobbied Congress, the new administration, and the department to "soften" the regulations, warning of dire consequences to access if the regulations were too burdensome. In this atmosphere, the regulations that emerged from the Health Care Finance Administration (HCFA, now known as the Centers for Medicare and Medicaid Services—CMS) were very different from prior CLIA '88 regulations, especially those concerning testing personnel. The new regulations had minimal requirements for testing personnel at all levels as well as minimal requirements for quality control and assessment that reduced the impact of this legislation on many laboratories.

HEALTH AND HUMAN SERVICES

The department of most interest to healthcare providers is the Department of Health and Human Services (HHS), which is charged with safeguarding the health of the public and providing those health services deemed essential to the maintenance of good health. The department identifies over 300 activities on its web site, examples of which are listed in Table 2.[5,6]

The organizational structure of HHS is very complex with seven assistant secretaries overseeing budget, emergency preparedness, legislative activities, public affairs, public health, and administration of the department. A complete list of all of the offices and agencies, each headed by an administrator, and their purposes and functions, can be found on the HHS web site at http://www.hhs.gov/about/index.html#agencies.

Table 1. Departments of the executive branch of the US Government

Agriculture
Commerce
Defense
Education
Energy
Health and Human Services
Homeland Security
Housing and Urban Development
Interior
Labor
State
Transportation
Treasury
Veterans Affairs

A number of these agencies are considered "regulatory" agencies because they can create and enforce regulations and rules. From this regulatory standpoint, there are three agencies within HHS that impact the practice of laboratory science and medicine: the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), and the Food and Drug Administration (FDA).

Centers for Disease Control and Prevention

The CDC is well-known for monitoring disease outbreaks, implementing disease prevention strategies, and maintaining national health statistics. It also provides immunization services, workplace safety, and environmental disease prevention guidance. The CDC monitors international disease transmission, with personnel stationed in more than 25 foreign countries. The CDC director is also the administrator of the Agency for Toxic Substances and Disease Registry, which helps prevent exposure to hazardous substances from waste sites on the US Environmental Protection Agency's National Priorities List.

Table 2. Activities currently under authority of the HHS

Health and social science research

Preventing disease, including immunization services

Assuring food and drug safety

Medicare (health insurance for elderly and disabled Americans)

Medicaid (health insurance for low-income people)

Financial assistance and services for low-income families

Improving maternal and infant health

Head Start (pre-school education and services)

Faith-based and community initiatives

This very science-oriented agency became involved in CLIA '88 by an act of Congress and it helps administer the CLIA '88 program with CMS and the FDA. Originally CDC was charged with the categorization of the laboratory tests to fit the three levels of testing, (waived, moderate, and high complexity), and to oversee the implementation of CLIA '88 standards. An advisory committee was established and its mission was stated as follows:

> *The Clinical Laboratory Improvement Advisory Committee shall provide scientific and technical advice and guidance to the Secretary; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; and the Administrator, Centers for Medicare and Medicaid Services, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.*[7]

Manufacturers found CDC slow to categorize new technology as they were particularly interested in their methods being classified as waived. CDC did issue a rule in 1995 describing criteria to use for waived testing but manufacturers commented that the criteria were too strict. Rather than wait for the final rule, the manufacturers lobbied Congress to transfer the categorization of laboratory tests to the FDA so it could be done as methods and devices were coming to market. FDA still has that authority.

Centers for Medicare and Medicaid Services

CMS administers Medicare, a federal healthcare coverage plan for the elderly, those with severe kidney damage who require dialysis, and people with certain disabilities. CMS also works with the states to administer Medicaid. Medicare is a federal insurance program, financed by salary deductions. When first created, Medicare had two parts: Part A that paid for hospital expenses and Part B to cover medical expenses. In 1997, Congress created a Part C known as Medicare Advantage. This option brought managed care and health savings accounts to Medicare. The current Congress added Part D to cover drug prescriptions costs.

CMS's oversight of Medicare includes controlling whether and how much Medicare reimburses for medical procedures, including laboratory services, using fee schedules and categorization systems such as diagnosis related groups (DRG) and the Ambulatory Payment Classifications (APC). The level of reimbursement for each of these approaches is in the rules and regulations that CMS writes. As another example of the rulemaking process, every year healthcare providers must monitor and respond to regulation changes that affect the levels of reimbursement. Some of these changes are made

Table 3. Responsibilities of the FDA

Biologics
Product and manufacturing establishment licensing
Safety of the nation's blood supply
Research to establish product standards and develop improved testing methods

Cosmetics
Safety
Labeling

Drugs
Product approvals
OTC and prescription drug labeling
Drug manufacturing standards

Foods
Labeling
Safety of all food products (except meat and poultry)
Bottled water

Medical devices
Pre-market approval of new devices
Manufacturing and performance standards
Tracking reports of device malfunctioning and serious adverse reactions

Radiation-emitting electronic products
Radiation-safety performance standards for microwave ovens, television receivers, diagnostic x-ray equipment, cabinet x-ray systems, laser products, ultrasonic therapy equipment, mercury vapor lamps, and sunlamps

Accrediting and inspecting mammography facilities

Veterinary products
Livestock feeds
Pet foods
Veterinary drugs and devices

through rulemaking and some are made by Congress, as that body passes the budget.

CMS also has authority for the regulation enforcement for CLIA '88. The Division of Laboratory Services is responsible for the certification and survey of clinical laboratories and is still writing final regulations.[7] The most recent regulations were published in January 2003 concerning quality systems requirements.

Food and Drug Administration

The FDA is a federal regulatory agency that monitors the safety and effectiveness of food, drinks, cosmetics, drugs, and medical devices. The agency regulates all of the products listed in Table 3.[8] The FDA is organized into "centers". The centers that impact the laboratory industry are the Center for Devices and Radiological Health with its Office of In Vitro Diagnostics Device Evaluation (OIVD), and the Center for Biological Evaluation and Research (CBER). CBER is responsible for all biologics which are defined as any material derived from human sources. Vaccines and blood products are two examples of biologics. CBER is the FDA center charged with keeping the US blood supply safe.

The FDA classifies all medical devices and OIVD is the center that is responsible for the classification of in vitro diagnostics methods and instruments. FDA classifications are designated as Class I, Class II, or Class III. Class I has the least regulation. Devices are classified by the potential risk of harming the user and by design. The simpler the design, the higher the probability that it will be classified as Class I. OIVD is the FDA center that determines whether a test will be classified as waived, moderately complex, or highly complex. Any test brought to market as an over-the-counter method (e.g. home pregnancy tests) is automatically classified as waived. For all other tests, the FDA looks at technical complexity and risk of harm due to erroneous results. In vitro diagnostics manufacturers typically apply for a CLIA '88 classification during the pre-market approval process. The FDA's decisions can be very controversial for the field and the manufacturer. However, this classification activity is not considered rulemaking so neither affected party can comment on the agency's decisions, although there are opportunities to appeal a decision. The FDA has been viewed as an obstructionist to new innovation, especially in drugs and medical devices. The Food and Drug Administration Modernization Act of 1997 was enacted by Congress to make the FDA more collaborative with the industries it regulates.

REGULATORY PROCESS

How did all these regulations affecting the practice of laboratory science and medicine come to exist? There are a number of reasons why a rule or regulation is written. Some laws are very prescriptive; they leave little doubt as to what Congress wants and how they want it to be implemented. Some laws are less defined, and regulations are needed to explain how to interpret and implement the law and how it will be enforced. When this is the case, Congress designates an agency to write and enforce rules and regulations. These regulations then become the law. CLIA '88 is a perfect example of this. The law itself is very brief; there was little understanding of how the law would work until the regulations were written. Because of the controversy that CLIA '88 stirred, it took four years before the final regulations were published. Additional paths to regulation include the following: an executive department or an agency can identify a need for regulation for a program within its scope of responsibility, or interested parties can petition an agency to write a rule or to request an interpretation of a law or existing rule.

Regardless of impetus, the process by which regulations are written is outlined in the APA. The APA outlines two processes: a formal rulemaking process and an informal process. The formal process is modeled after a trial and is rarely used. Usually the informal rulemaking or "notice and comment" process is used (Table 4).

Before the agency can publish the proposed rule, the language must be reviewed within the agency by the administrator of the agency, the secretary of the executive department for that agency, the department's legal counsel and finally the Office of Management and Budget. This office is concerned with the economic impact of the regulation but also how the rule conforms to the administration's views and philosophy.[9]

Writing regulations can be a long, drawn out process if there are many interests and concerns to be addressed. This was the case with CLIA '88. APA requires agencies to provide a mechanism for all interested and affected parties to make comments, suggest changes, or protest any or all of the regulation. When the CLIA-proposed rules were published in February of 1992, CMS received thousands of comments about such elements as the laboratory director qualifications, the testing personnel requirements, and quality control.

Additionally, APA requires that agencies review and consider every public comment. An agency can opt to revise draft regulations based on the comments and then issue a final

rule. In the preamble to the final rule, the agency may discuss the comments and explain whether they addressed the concern or why the comment was not incorporated into the regulation. The final rule must be published in the *Federal Register.* The final rule can be published with or without a comment period. If there is a comment period, the comments received are reviewed and filed. Because the rule is final, the agency will not make any changes based on the comments. The agency allows comments when they know that the final rule is controversial or when they anticipate that the regulation will be opened in the near future.

The final rules and regulations are published in the *Code of Federal Regulations (CFR)* to be codified. The *CFR* is the repository of all of the rules published in the *Federal Register* by the departments of the executive branch and any federal agency. There are 50 volumes or titles, representing the areas subject to federal regulation (Table 5).[10] CLIA regulations are in Title 42 and FDA regulations are in Title 21.

Every agency in the federal government must prepare a report detailing the regulations that the agency is working on or has recently revised. This report is published in the *Federal Register* as the "Unified Agenda of Federal and Regulatory and Deregulatory Actions". This report is usually published in April and October and is an excellent resource for tracking the status of any agency and/or regulation that affects your professional or personal life.

Table 4. Outline of the APA informal rulemaking process

1. An agency must publish a notice announcing intention to write a regulation. This advanced notice is referred to as the "Notice of Proposed Rulemaking" and must be published in the *Federal Register*, the government's daily newsletter.

2. The regulation must be published at least 30 days before it takes effect, with a public comment period. In this pre-announced amount of time, anyone who is interested can submit comments, both positive and negative. Typical public comment periods are 60 days to 90 days. (Agencies can also hold meetings to discuss the rule or potential changes to an existing rule as a means of soliciting public comments.)

NEGOTIATED RULEMAKING

The APA informal process was meant to provide a simple and quick way to craft rules and regulations. Over time, the lengthy responses that agencies had to make to the comments and the legal action that virtually anyone could take against any regulation led to a search for another approach.

The purpose for the committee constructed under the FACA is to reach consensus on the language of the regulation. Consensus can be defined differently by each committee but should have the notion that everyone can live with the agreed-upon language. The act outlines criteria to determine whether a negotiated rulemaking or "neg reg" approach will work. The process is outlined in Table 6.

Minutes of all committees are published in the *Federal Register* and are open to the public. Only committee members can speak. Members of the audience or support personnel for the committee member can speak if given permission by the committee; otherwise they must talk to a committee member and that person will convey their thoughts.

An example of this process was the Negotiated Rulemaking Committee on the Medicare Part B clinical laboratory payment. This committee consisted of individuals associated with national organizations representing parties affected by a change in reimbursement. They included all of the laboratory associations, the American Medical Association and other physician practice groups, the American Hospital Association, and the AARP (representing the beneficiary). Consensus was defined by this committee as being able to live with the language when the entire regulation was written. The committee met for almost two years and actually wrote the National Coverage Determinations published with the regulation. The process was long due to the contentiousness of many issues surrounding how to submit a claim for laboratory services to Medicare, in particular how to document medical necessity. The regulations were finally published in the November 2001 *Federal Register*.

DIFFERENCES IN APPROACH

Negotiated rulemaking tends to yield regulations that are more technically correct and fairer. Because the process uses the input of the people who will live with the consequences of the regulations (and are living with current regulations), the new rule usually reflects some of the needs of all of the parties, clarifies past confusion, and corrects problems with old regulations or issues. In addition, the process of notice and comment goes more smoothly since everyone on the committee promises to support

the rule if there are no substantive changes when it is published. There appears to be less litigation over the rule and more compliance - or at least fewer complaints about complying.

However, "neg reg" is much more expensive than the informal process of the APA. The cost of holding meetings and the commitment of agency personnel and legal counsel are considerable. Furthermore, there is the risk that regulations will not accomplish all that the agency wanted and the agency will still have to use APA procedures in the future. Agency experience has shown that the "neg reg" process does produce useful, easily implemented regulations that save litigation

Table 5. *Code of Federal Regulations* index of rules and regulations by title

TITLE revised Jan 1	Area
1	General Provisions
2	Grants and Agreements
3	The President
4	Accounts
5	Administrative Personnel
6	Homeland Security
7	Agriculture
8	Aliens and Nationality
9	Animals and Animal Products
10	Energy
11	Federal Elections
12	Banks and Banking
13	Business Credit and Assistance
14	Aeronautics and Space
15	Commerce and Foreign Trade
16	Commercial Practices

TITLE revised Apr 1	Area
17	Commodity and Securities Exchanges
18	Conservation of Power and Water Resources
19	Customs Duties
20	Employees' Benefits
21	Food and Drugs
22	Foreign Relations
23	Highways
24	Housing and Urban Development
25	Indians
26	Internal Revenue
27	Alcohol, Tobacco Products and Firearms

TITLE revised Jul 1	Area
28	Judicial Administration
29	Labor
30	Mineral Resources
31	Money and Finance: Treasury
32	National Defense
33	Navigation and Navigable Waters
34	Education
35	Panama Canal
36	Parks, Forests, and Public Property
37	Patents, Trademarks, and Copyrights
38	Pensions, Bonuses, and Veterans' Relief
39	Postal Service
40	Protection of Environment
41	Public Contracts and Property Management

TITLE revised Oct 1	Area
42	Public Health
43	Public Lands: Interior
44	Emergency Management and Assistance
45	Public Welfare
46	Shipping
47	Telecommunication
48	Federal Acquisitions Regulations System
49	Transportation
50	Wildlife and Fisheries

The *Code of Federal Regulations* is divided in 50 titles. These titles identify the areas for which federal regulations are written. The 50 titles are divided into four volumes which are updated annually. The dates above represent the quarter in which the updates occur.

and enforcement expenses. Some agencies use this more frequently than others; CMS has used it for a number of its rules but only once for the laboratory.

Table 6. FACA process to determine "neg reg" feasibility and application

The head of the agency should determine the following.

1. A need for a rule that has been identified by the agency or by Congress instructing the agency
2. Parties of interest who can be identified and are limited in number (12-25)
3. A potential that a balanced committee can be convened and would be willing to negotiate
4. Reasonable likelihood that consensus would be reached in a predictable period of time that wouldn't delay the issuance of the regulation
5. Resources within the agency to devote to the process and intent to use the results to write the regulation

Once it has been determined that "neg reg" is feasible and in the public's best interest, the following steps are taken:

1. A neutral convener is selected who will identify all of the parties and act as the facilitator for the group.
2. A notice is published in the *Federal Register* announcing the agency's intent to use "neg reg" to write a rule, a description of the topic, those identified to sit on the committee, the schedule, and a call for comments on both the intent to establish the committee and the proposed members.

Other persons than those identified by the convener are allowed to apply to the committee and depending on when they apply, can be added by the convener or if need to be added by consensus of the committee.

CONCLUSION

Regulatory agencies and their regulations comprise a majority of the rules and laws we live with in the United States. This process, while not apolitical, is conducted by unelected staff and traditionally, input has been given after the fact. Developing regulations are conducted under the auspices of either the APA or the Negotiated Rulemaking Act. The regulations and any intent to publish new or amended regulations can be found in the *Federal Register* and are codified in the *Code of Federal Regulations*. The impact of these regulations is greater than most of the legislation enacted by Congress.

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