Federal Government Impact in the Clinical Laboratory

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Lacking specific reference in the Constitution, healthcare is fundamentally the right of the state and not the federal government. Federal intervention has therefore used a discordant approach to addressing national concerns and responsibilities. Focus: Government Regulations explains this complex array of issues and agencies as they affect our profession. This brief explanation of the processes and agencies that influence healthcare delivery may be beneficial as providers navigate twenty-first century American healthcare.

To be both a citizen and a scientist is a balancing act. The knowledge base in the clinical sciences doubles approximately every four years. With so much time and effort devoted to currency and competency, it is difficult to segregate time and effort to understanding and influencing the role of government. This is especially true in the face of cynicism and apathy.

Governmental oversight continues to intensify. No other single entity has so much power. Physicians may desire additional testing. Patients may wish for faster turnaround times. Hospital administrators may hope for lower costs. Governmental agencies exert their influence from the type of pipette used to the educational background of the practitioner to reporting and retrieval mechanisms.

The first article is a compendium of some of the major legislative initiatives that impact the clinical laboratory. The second reviews the structure of the legislative realities as a bill becomes a law, providing insight and reducing our reluctance to work within the system, and the third explains how a law is actualized through regulatory agencies.

LEARNING OBJECTIVES

1. List the major agencies that provide oversight or have financial implications to the clinical laboratory.
2. Compare and contrast the processes used in the Administrative Procedures Act (APA) and the Negotiated Rulemaking Act ("neg reg").
3. Explain the roles of the CDC, FDA, and CMS in the development of clinical laboratory test categorization
4. Describe how a bill becomes a federal law.
5. Discriminate among the various types of laws and regulations.
6. Identify the various components of a federal law's codified form.
7. List the influences that affect a law after it is passed.
8. Follow the post-enactment changes that occur to a law during the regulatory phase.
9. Identify at least four laws that have impact on clinical laboratory personnel.

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