



HEALTH CARE POLICY

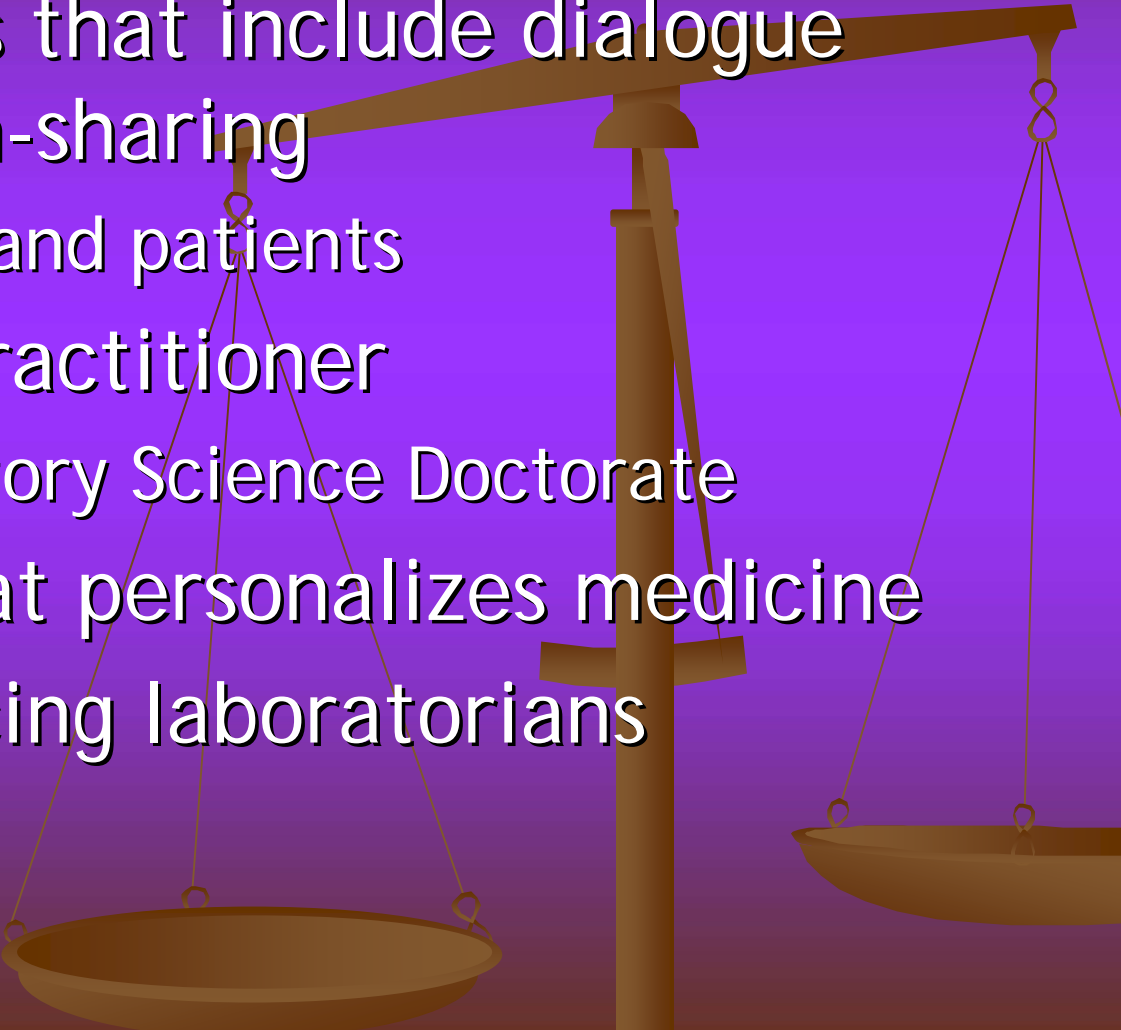
**LEGISLATIVE AND REGULATORY
UPDATE**

REMODELING OF HEALTH CARE

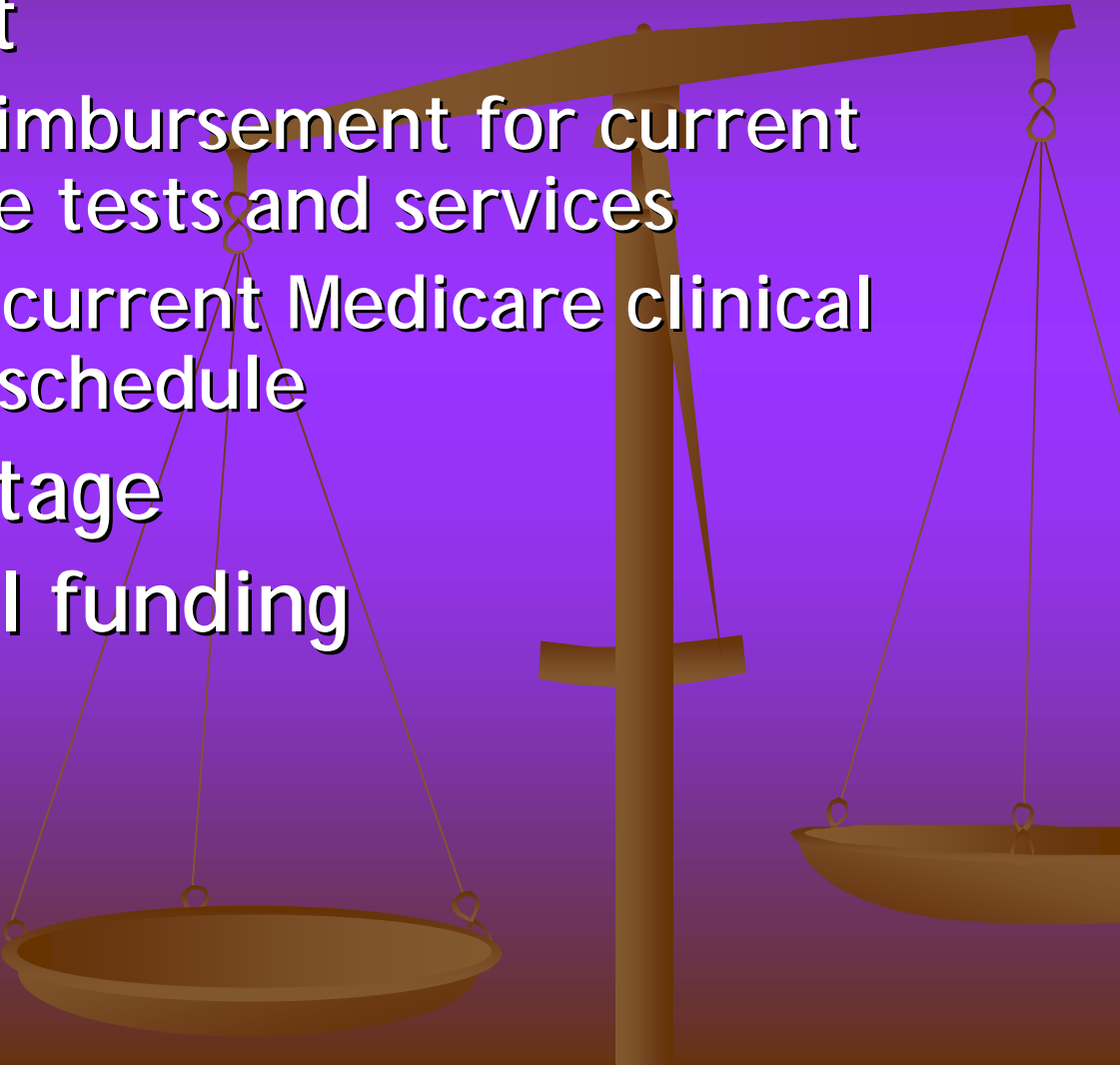
- Shift from acute care to prevention (wellness) and chronic care
- Consumer activism
 - Fueled by Boomer generation's characteristics
 - Impatient
 - Highly educated
 - Self-directed
 - Refusing to age (or grow up)
- Rising costs



REMODELING OF LABORATORY SERVICES

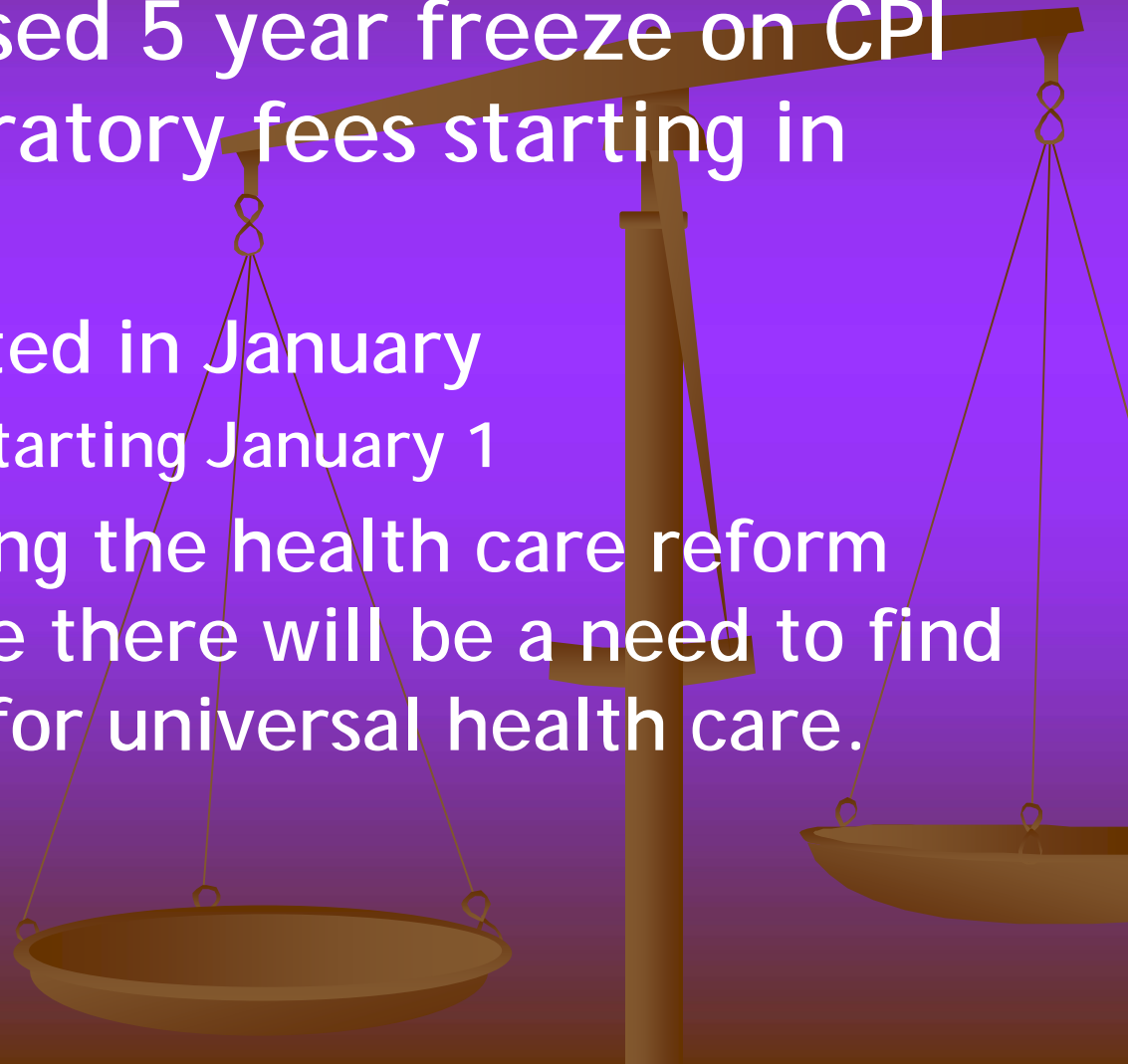
- Business models that include dialogue and information-sharing
 - With providers and patients
 - New levels of practitioner
 - Clinical Laboratory Science Doctorate
 - New science that personalizes medicine
 - Other issues facing laboratorians
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ISSUES EFFECTING CLINICAL LABORATORIES

- Reimbursement
 - Appropriate reimbursement for current tests and future tests and services
 - Modernize the current Medicare clinical laboratory fee schedule
 - Personnel Shortage
 - Title VII and VIII funding
 - CLIA
 - Genetic testing
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CPI FREEZE

- Congress imposed 5 year freeze on CPI update of laboratory fees starting in 2004
 - Freeze was lifted in January
 - 4.5% update starting January 1
 - We are watching the health care reform efforts because there will be a need to find money to pay for universal health care.



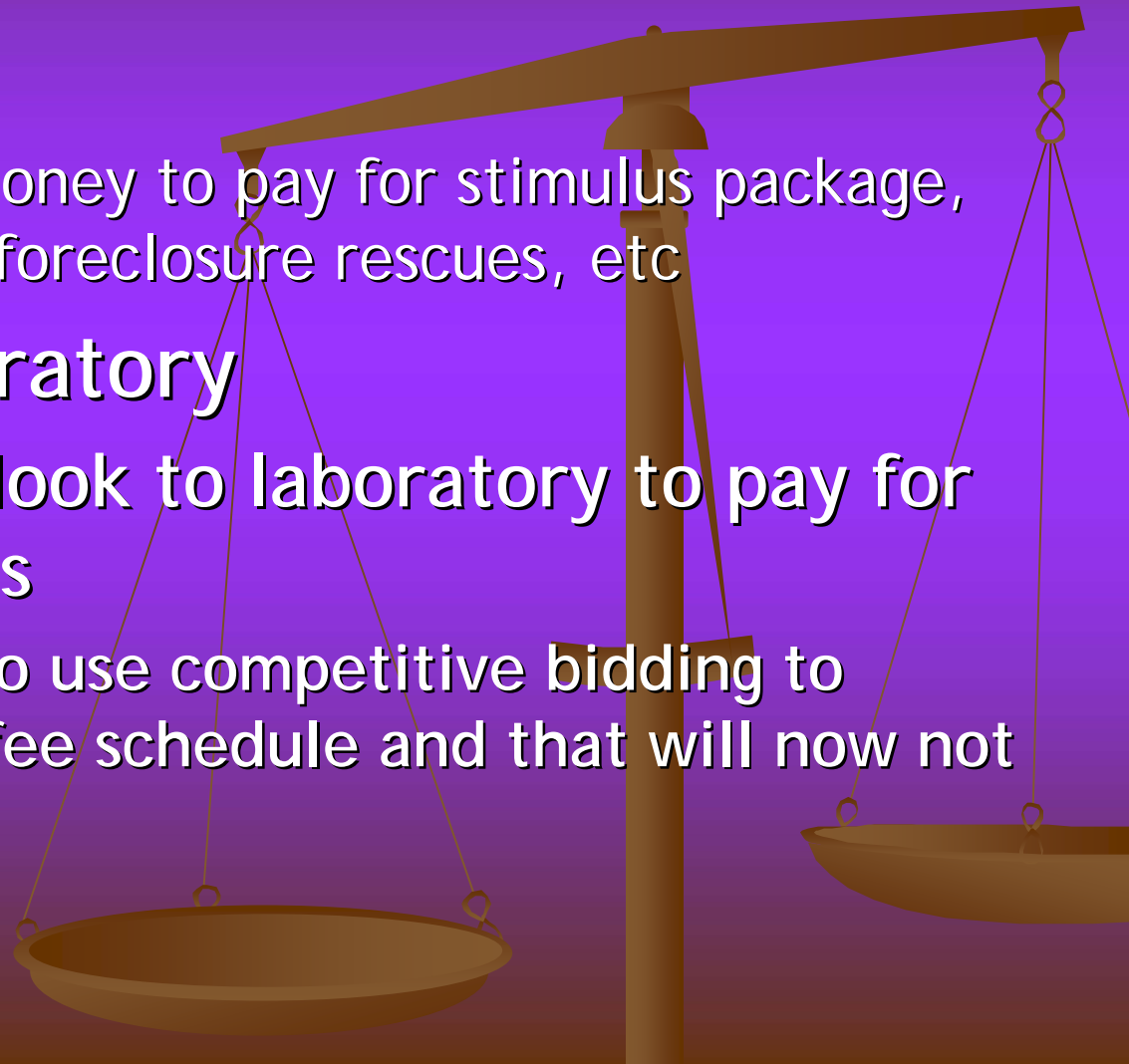
STRUGGLES FOR CONGRESS 2009

■ Record deficit

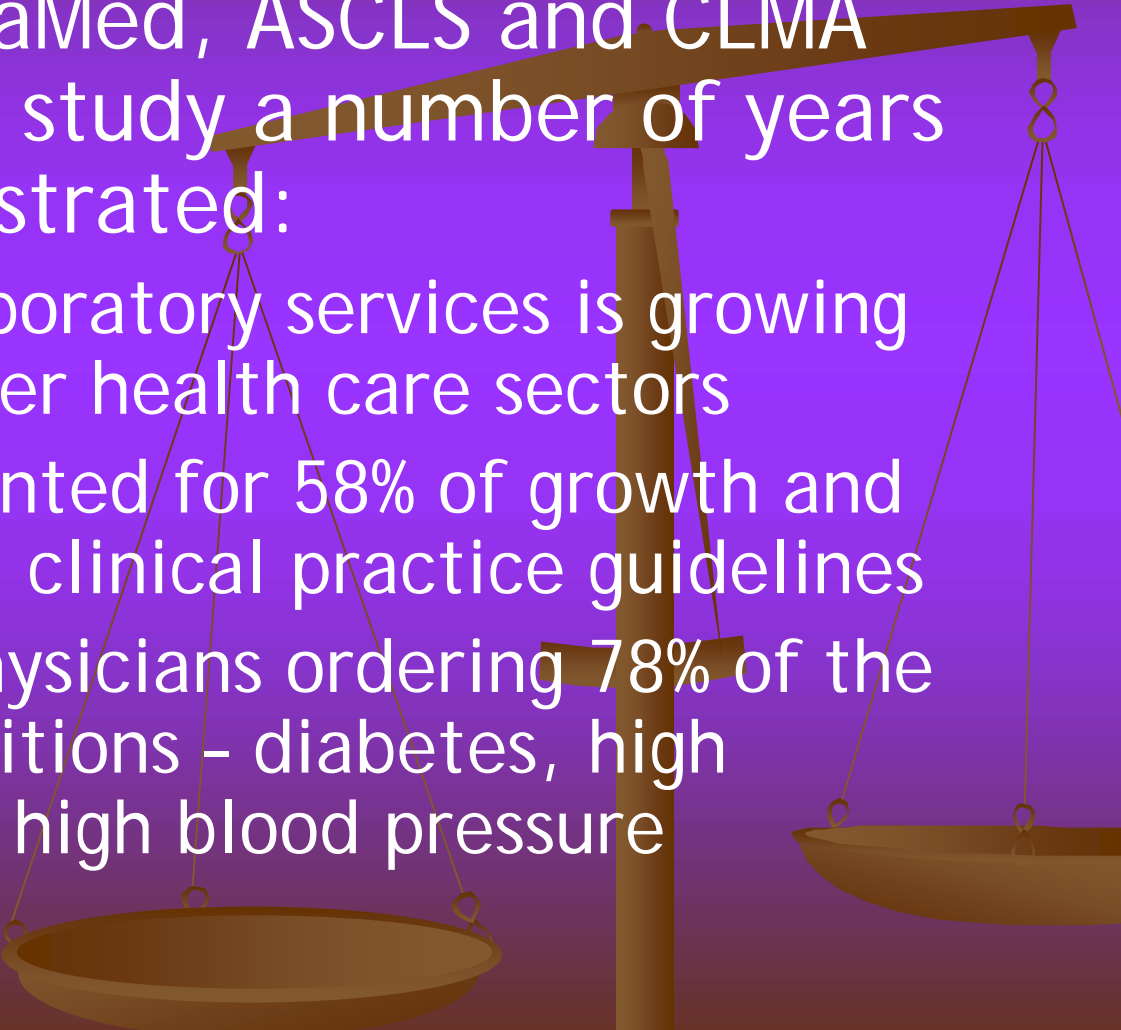
- Need to find money to pay for stimulus package, bailout, home foreclosure rescues, etc

■ Impact on laboratory

- Congress may look to laboratory to pay for Medicare needs
 - CMS planned to use competitive bidding to decrease the fee schedule and that will now not happen

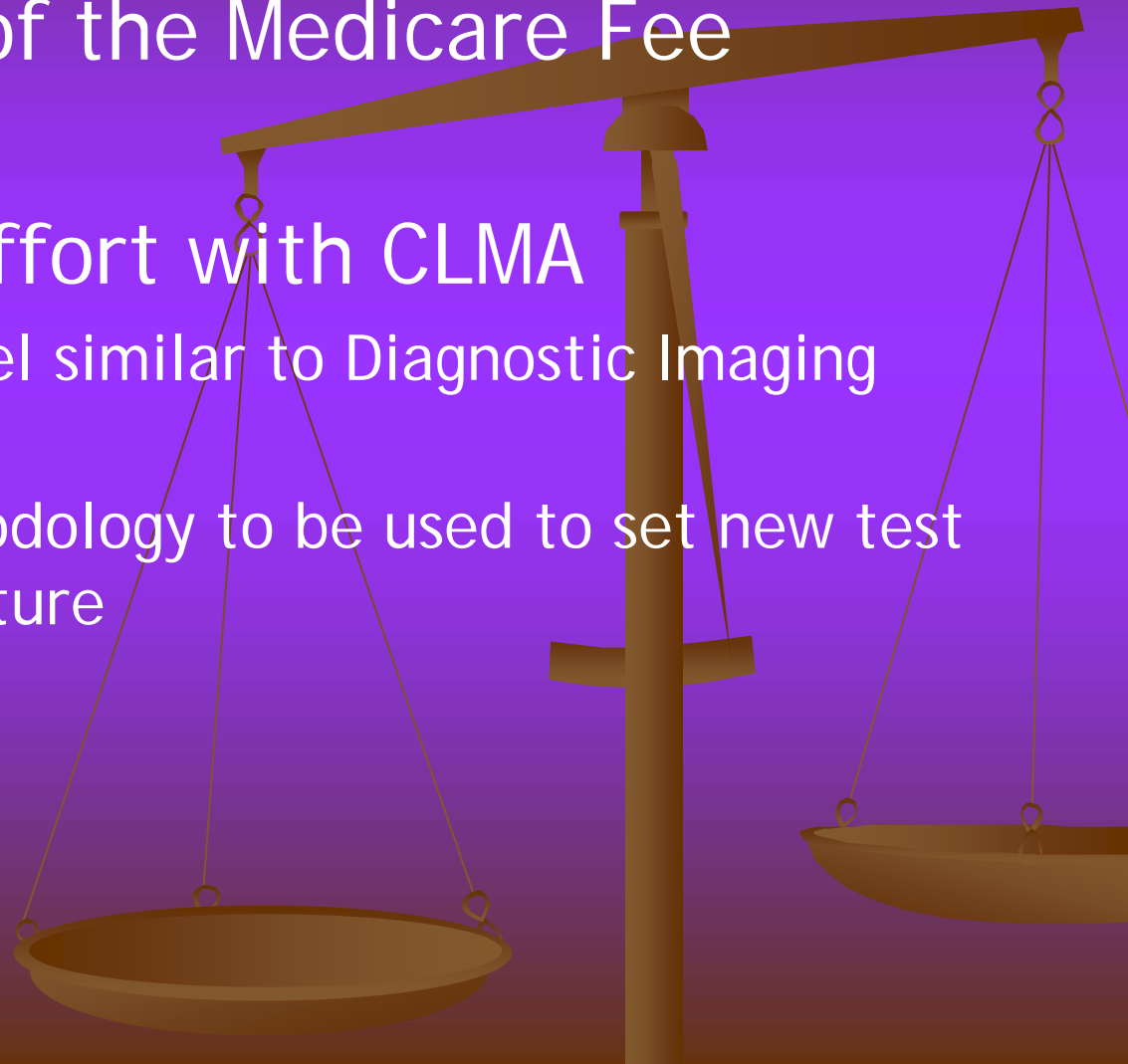


FAIR REIMBURSEMENT

- ACLA, AAB, AdvaMed, ASCLS and CLMA commissioned a study a number of years ago that demonstrated:
 - Spending for laboratory services is growing slower than other health care sectors
 - Ten tests accounted for 58% of growth and were tests from clinical practice guidelines
 - Primary care physicians ordering 78% of the tests for 3 conditions - diabetes, high cholesterol and high blood pressure
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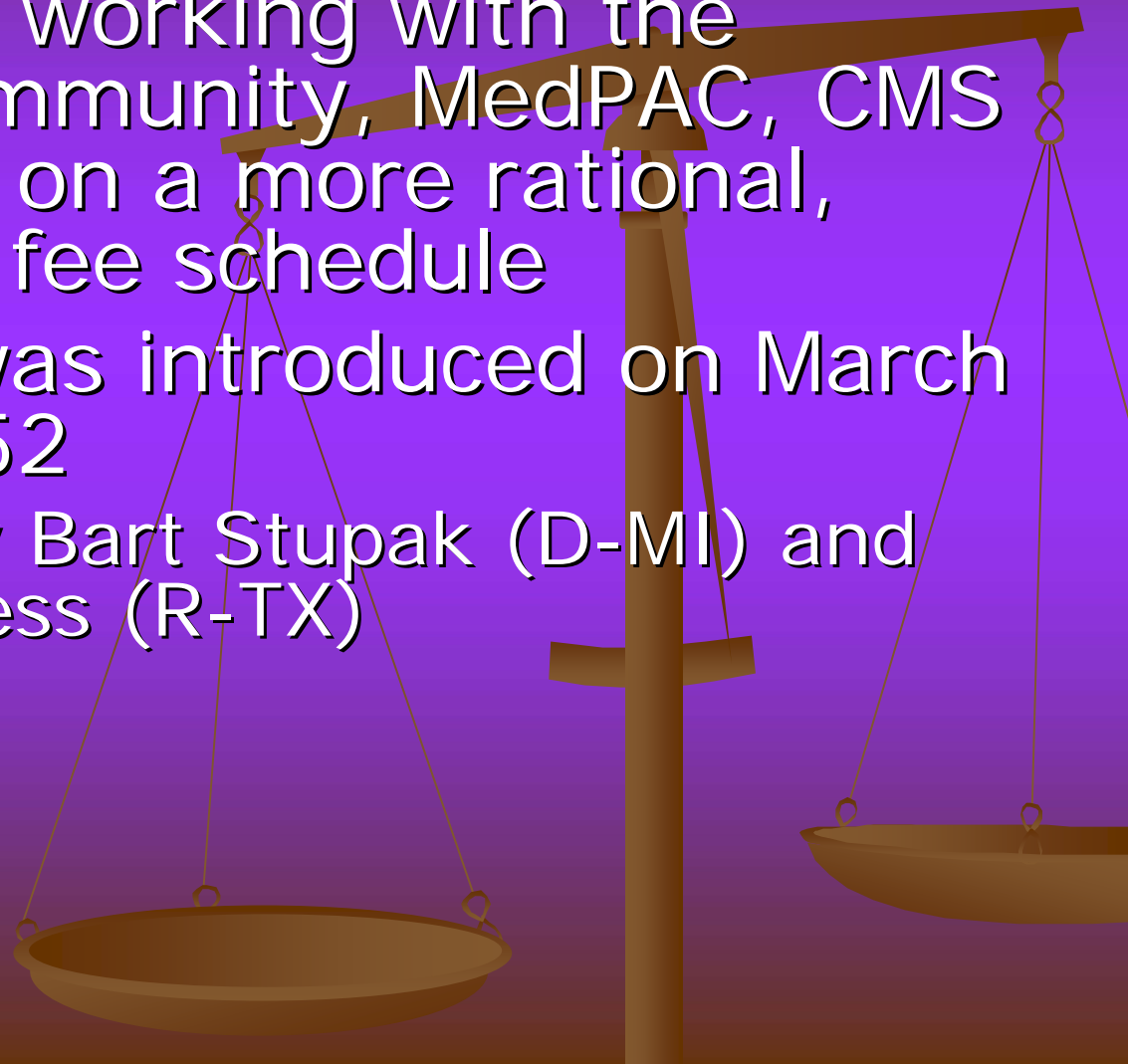
FAIR REIMBURSEMENT

- Modernization of the Medicare Fee Schedule
- Collaborative effort with CLMA
 - RVU-type model similar to Diagnostic Imaging model
 - Rational methodology to be used to set new test fees for the future



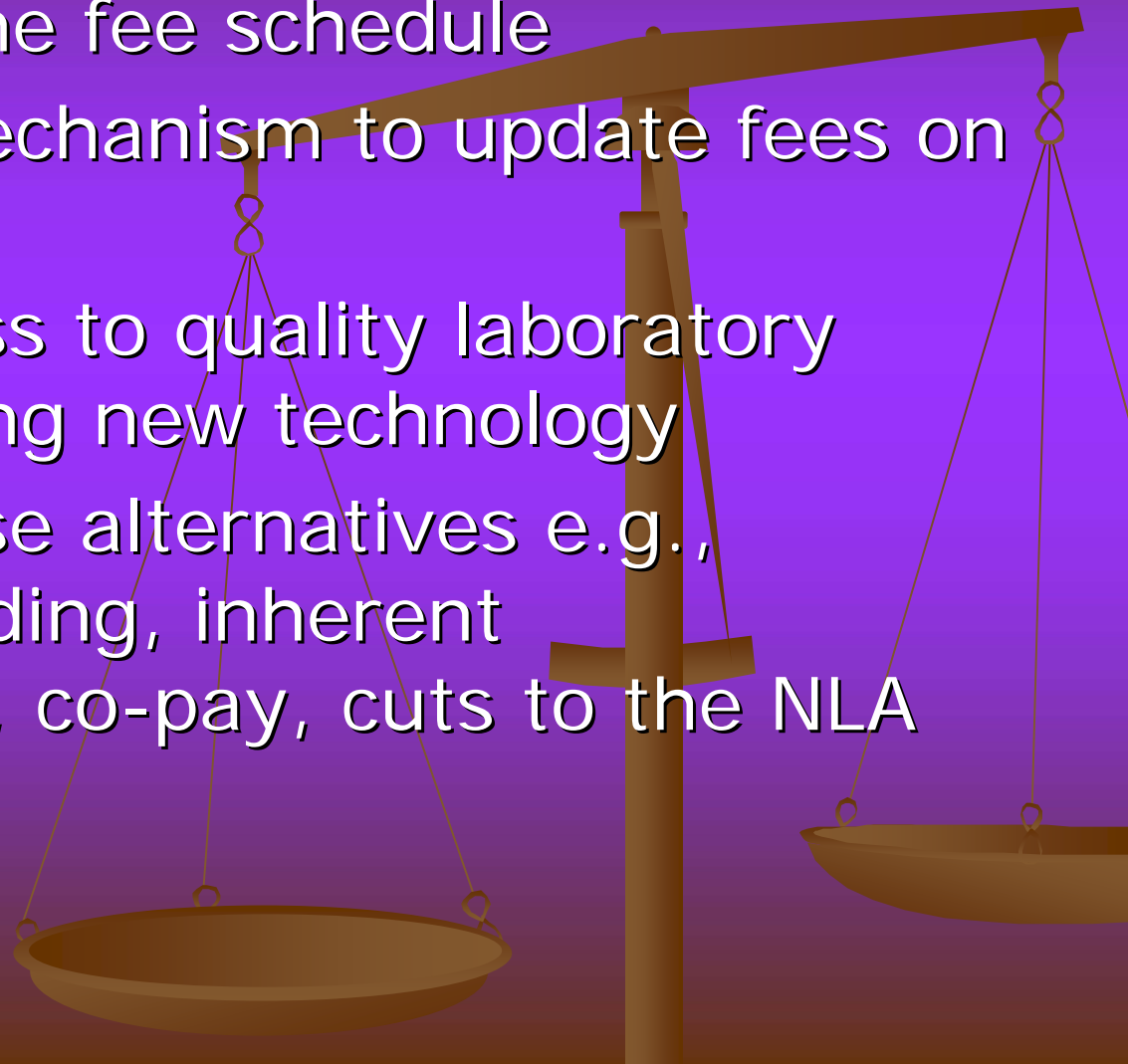
CLMA/ASCLS EFFORT

- Committed to working with the laboratory community, MedPAC, CMS and Congress on a more rational, cost-effective fee schedule
- A House bill was introduced on March 12th; H.R. 1452
 - Sponsored by Bart Stupak (D-MI) and Michael Burgess (R-TX)

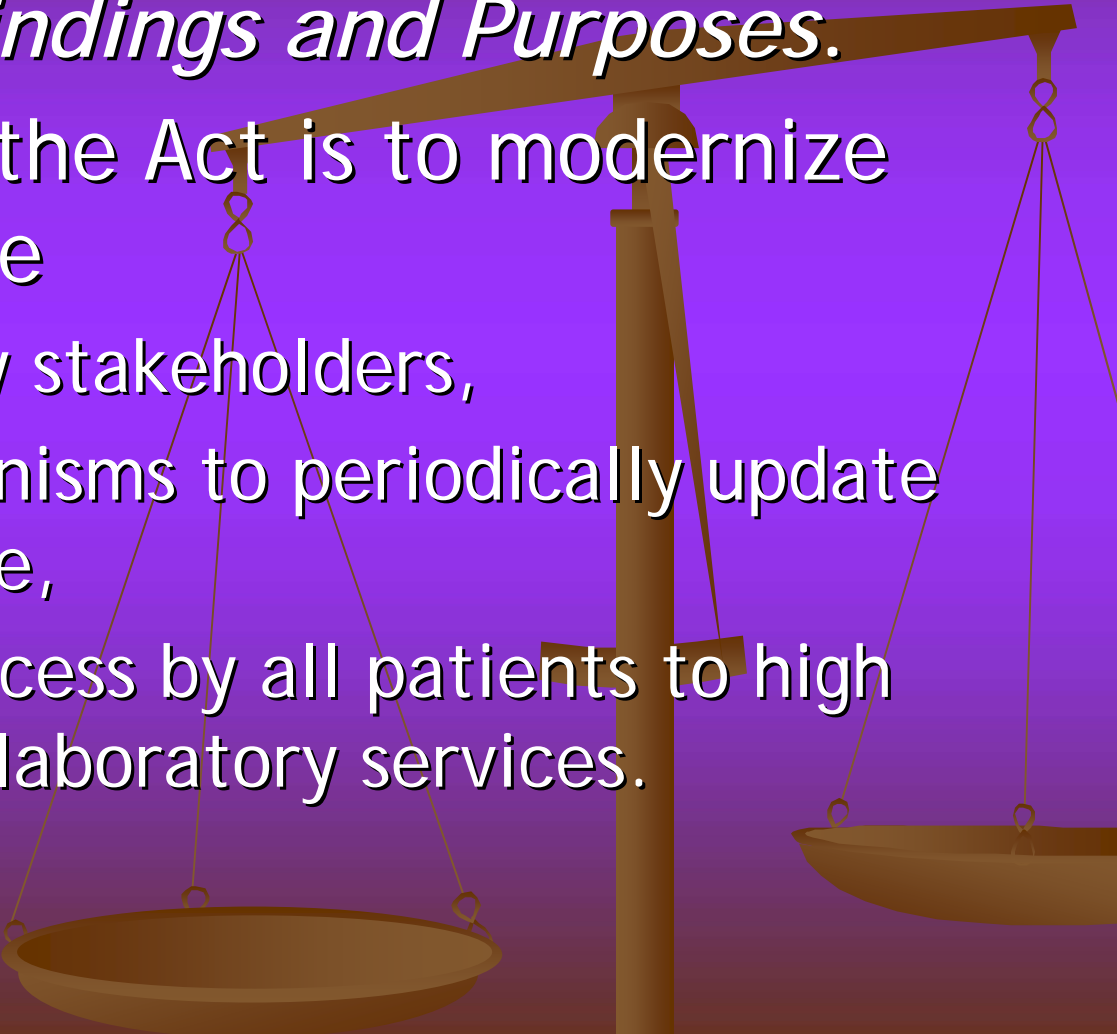


Goals of the Legislation

- To rationalize the fee schedule
- To provide a mechanism to update fees on a regular basis
- To ensure access to quality laboratory services including new technology
- To counter worse alternatives e.g., competitive bidding, inherent reasonableness, co-pay, cuts to the NLA



H.R. 1452 SECTIONS

- Section 101. *Findings and Purposes.*
 - The purpose of the Act is to modernize this fee schedule
 - by involving key stakeholders,
 - creating mechanisms to periodically update the fee schedule,
 - and ensuring access by all patients to high quality clinical laboratory services.
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H.R. 1452 SECTIONS

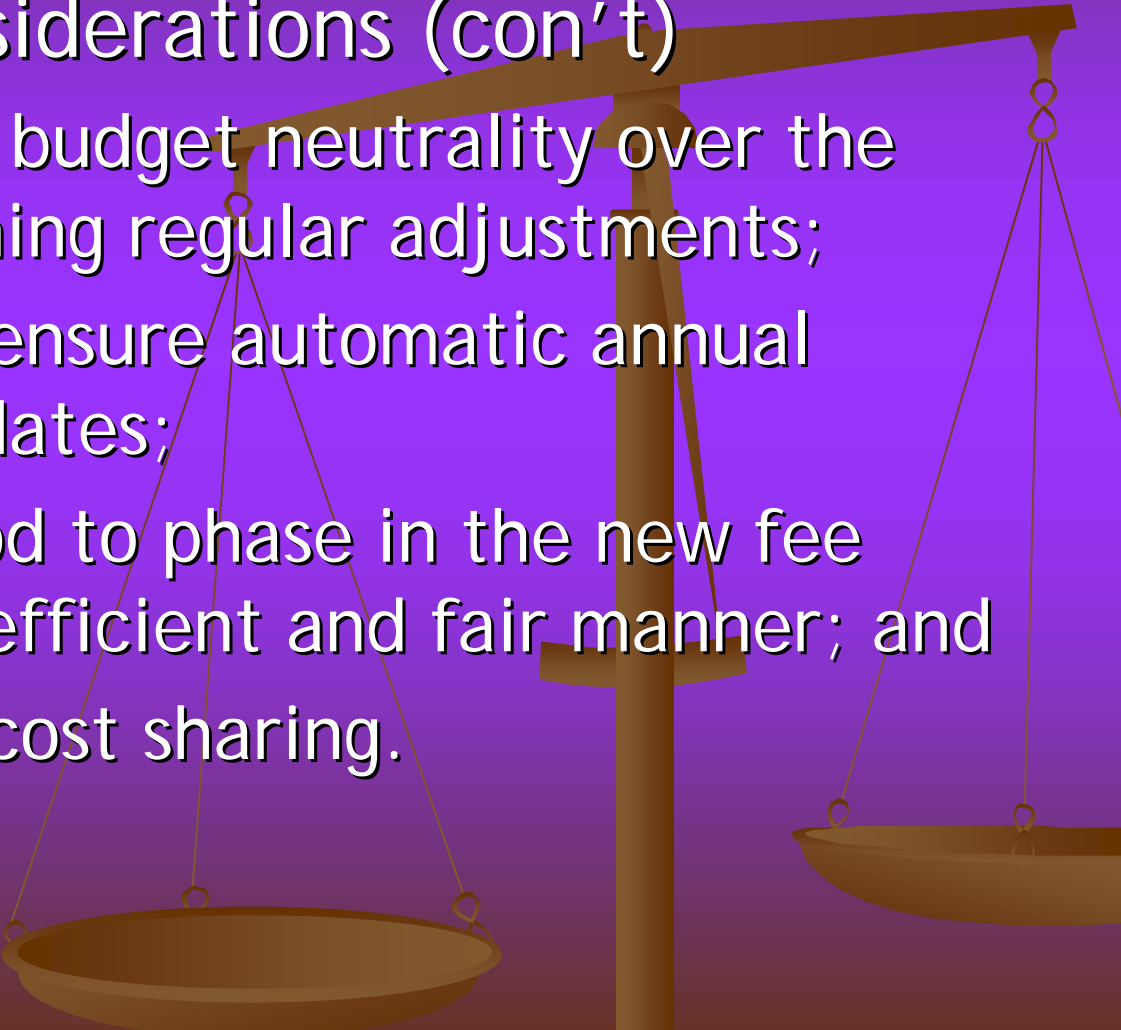


- Section 102. *Process for the Modernization of the Fee Schedule for Clinical Diagnostic Laboratory Tests.*
- This section requires the Secretary of the Department of Health and Human Services (the "Secretary") to:
 - establish a negotiated rulemaking committee (the "Committee"),
 - submit a report to the Congress within 24 months regarding the result of the Committee's negotiations,
 - and promulgate a regulation implementing the modernized clinical laboratory fee schedule if the Committee reaches consensus.

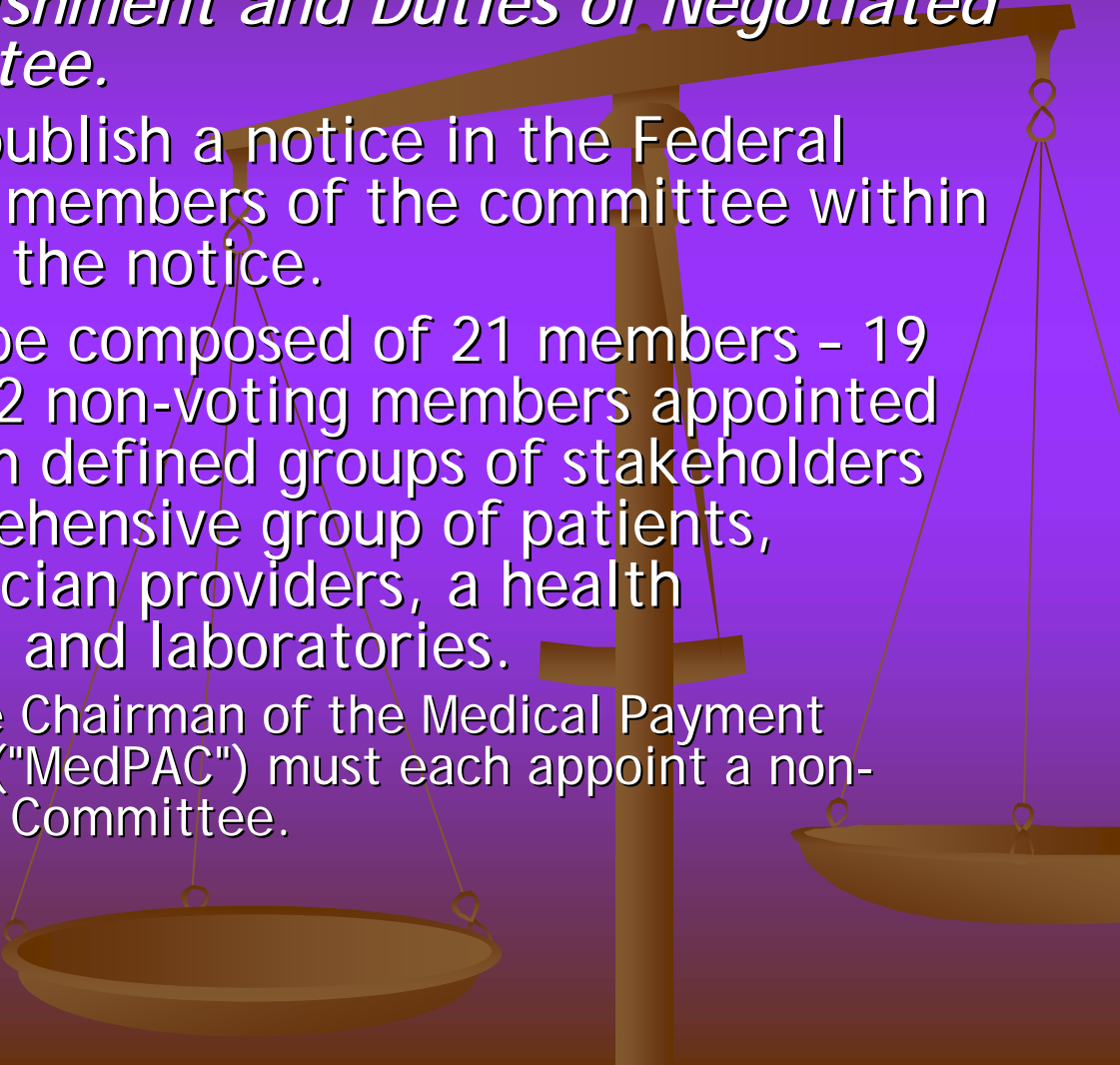
H.R. 1452 SECTIONS

- The Neg Reg Committee must include the following in its modernized fee schedule:
 - Access by all Part B beneficiaries to quality laboratory services.
 - Design that establishes a single, rational and national fee schedule.
 - Mechanisms to periodically revise the fee schedule to reflect new technology and account for changes in cost, value and utilization of laboratory tests;
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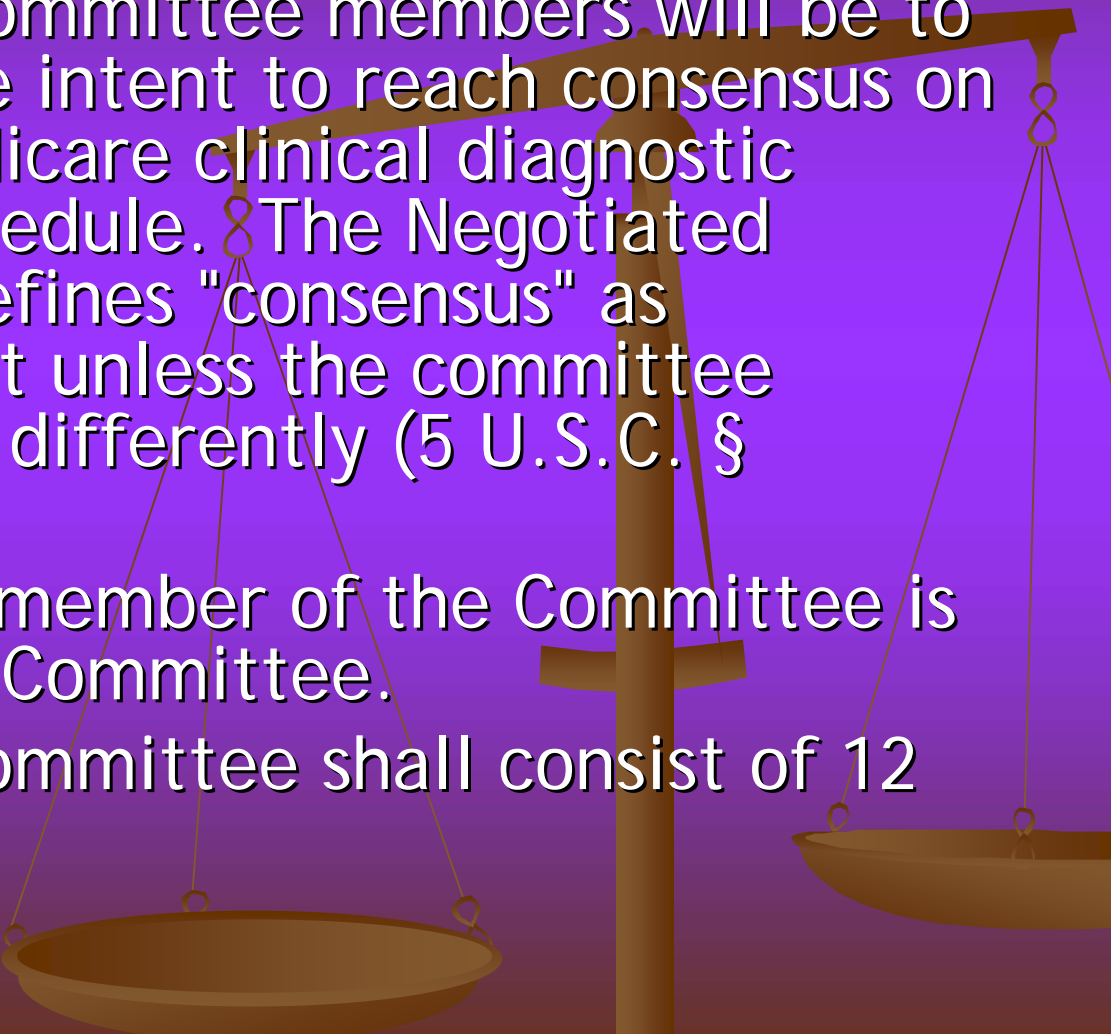
H.R. 1452 SECTIONS

- Committee considerations (con't)
 - Maintenance of budget neutrality over the first year assuming regular adjustments;
 - Mechanisms to ensure automatic annual inflationary updates;
 - Transition period to phase in the new fee schedule in an efficient and fair manner; and
 - No beneficiary cost sharing.
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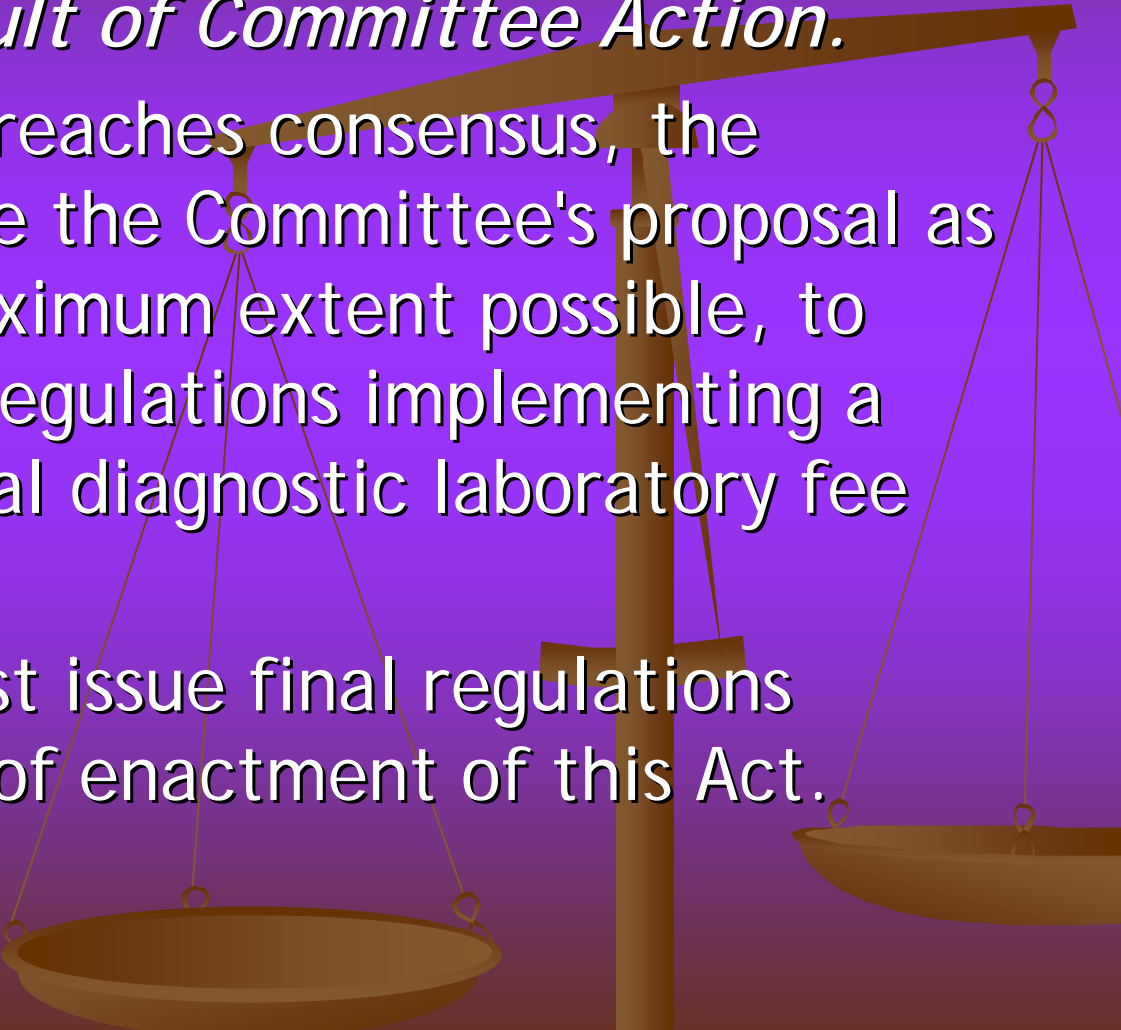
H.R. 1452 SECTIONS

- Section 103. *Establishment and Duties of Negotiated Rulemaking Committee.*
 - The Secretary must publish a notice in the Federal Register and appoint members of the committee within 60 days of publishing the notice.
 - The Committee will be composed of 21 members - 19 voting members and 2 non-voting members appointed by the Secretary from defined groups of stakeholders that include a comprehensive group of patients, physicians, non-physician providers, a health economist, hospitals, and laboratories.
 - The Secretary and the Chairman of the Medical Payment Advisory Commission ("MedPAC") must each appoint a non-voting member of the Committee.
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H.R. 1452 SECTIONS

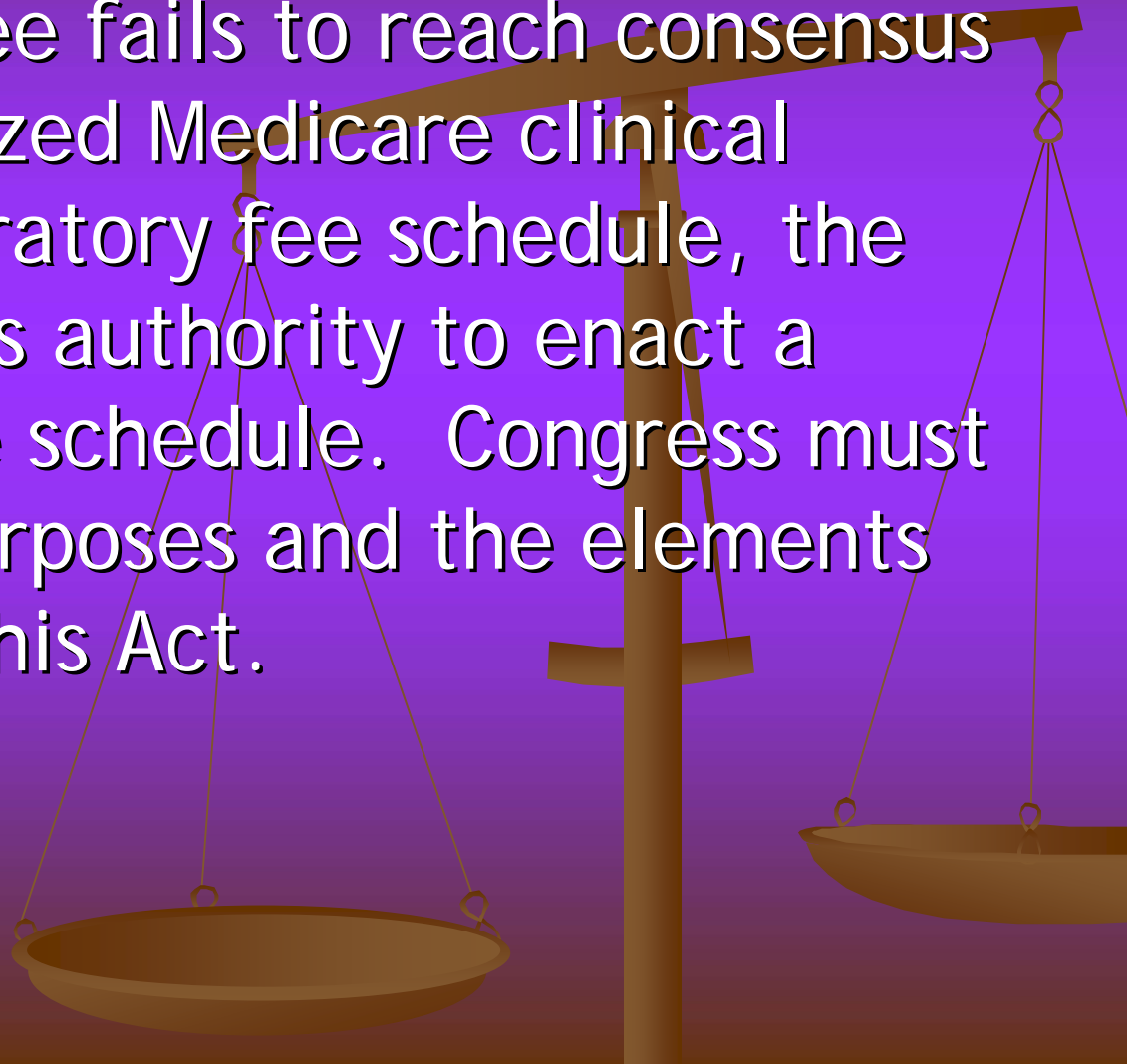
- The duty of the Committee members will be to negotiate with the intent to reach consensus on a modernized Medicare clinical diagnostic laboratory fee schedule. The Negotiated Rulemaking Act defines "consensus" as unanimous consent unless the committee defines consensus differently (5 U.S.C. § 562(2)).
 - The term of each member of the Committee is for the life of the Committee.
 - Quorum for the Committee shall consist of 12 members
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H.R. 1452 SECTIONS

- Section 104. *Result of Committee Action.*
 - If the Committee reaches consensus, the Secretary must use the Committee's proposal as a basis, to the maximum extent possible, to promulgate final regulations implementing a modernized clinical diagnostic laboratory fee schedule.
 - The Secretary must issue final regulations within 36 months of enactment of this Act.
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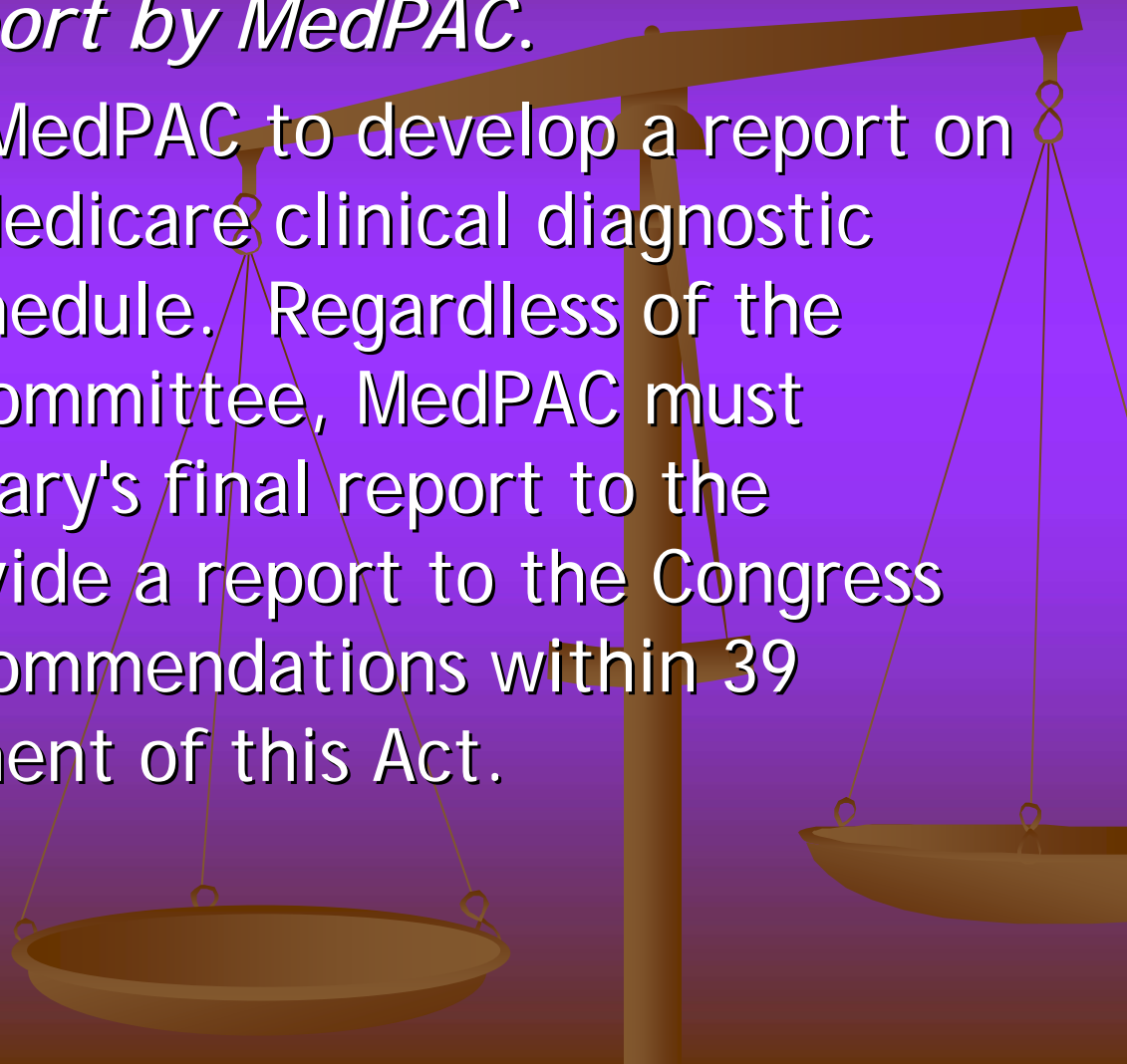
H.R. 1452 SECTIONS

- If the Committee fails to reach consensus on the modernized Medicare clinical diagnostic laboratory fee schedule, the Congress retains authority to enact a modernized fee schedule. Congress must consider the purposes and the elements to consider in this Act.

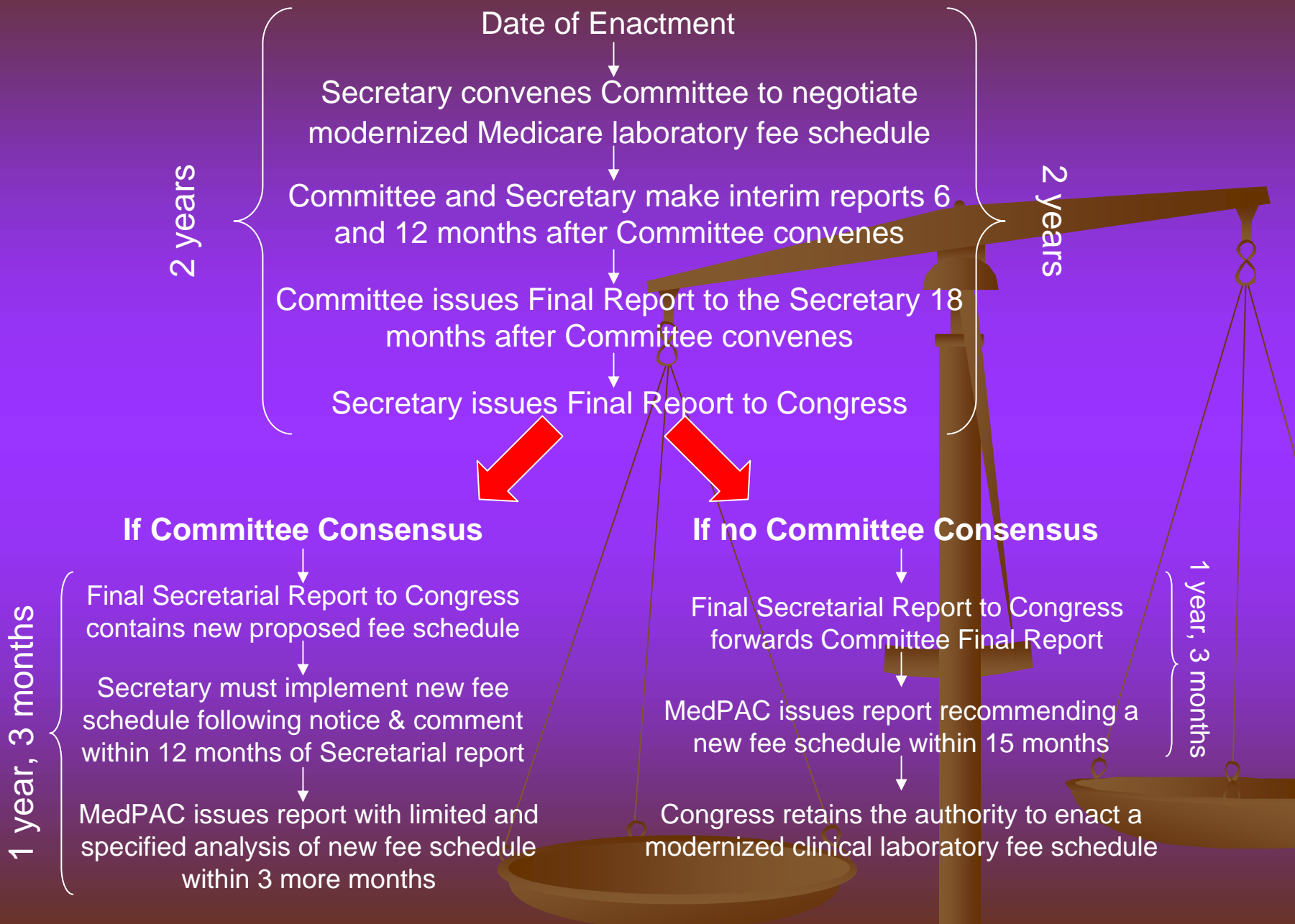


H.R. 1452 SECTIONS

- Section 105. *Report by MedPAC.*
- The Act requires MedPAC to develop a report on the modernized Medicare clinical diagnostic laboratory fee schedule. Regardless of the outcome of the Committee, MedPAC must review the Secretary's final report to the Congress and provide a report to the Congress containing its recommendations within 39 months of enactment of this Act.

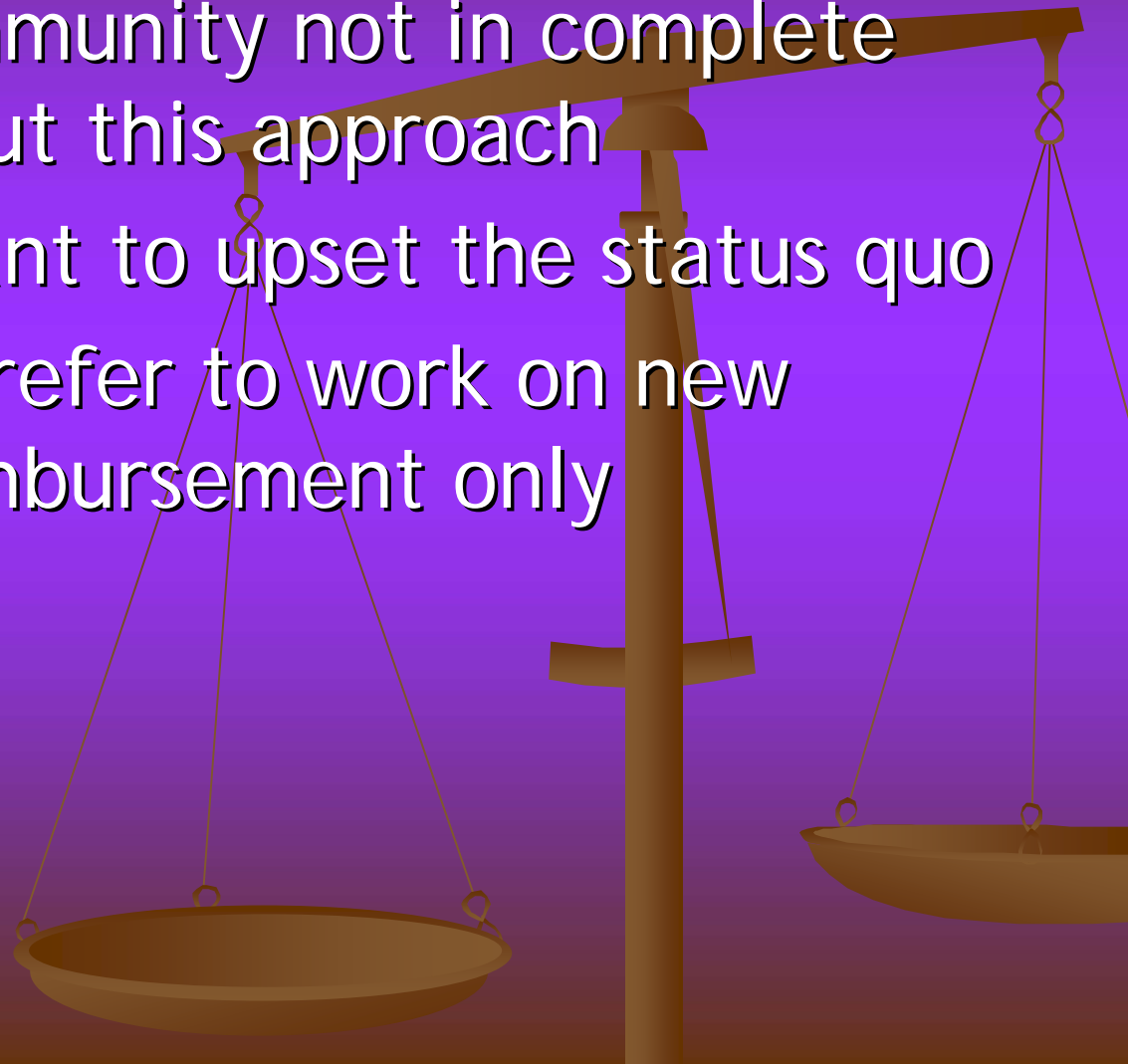


Overview of H.R. 1452

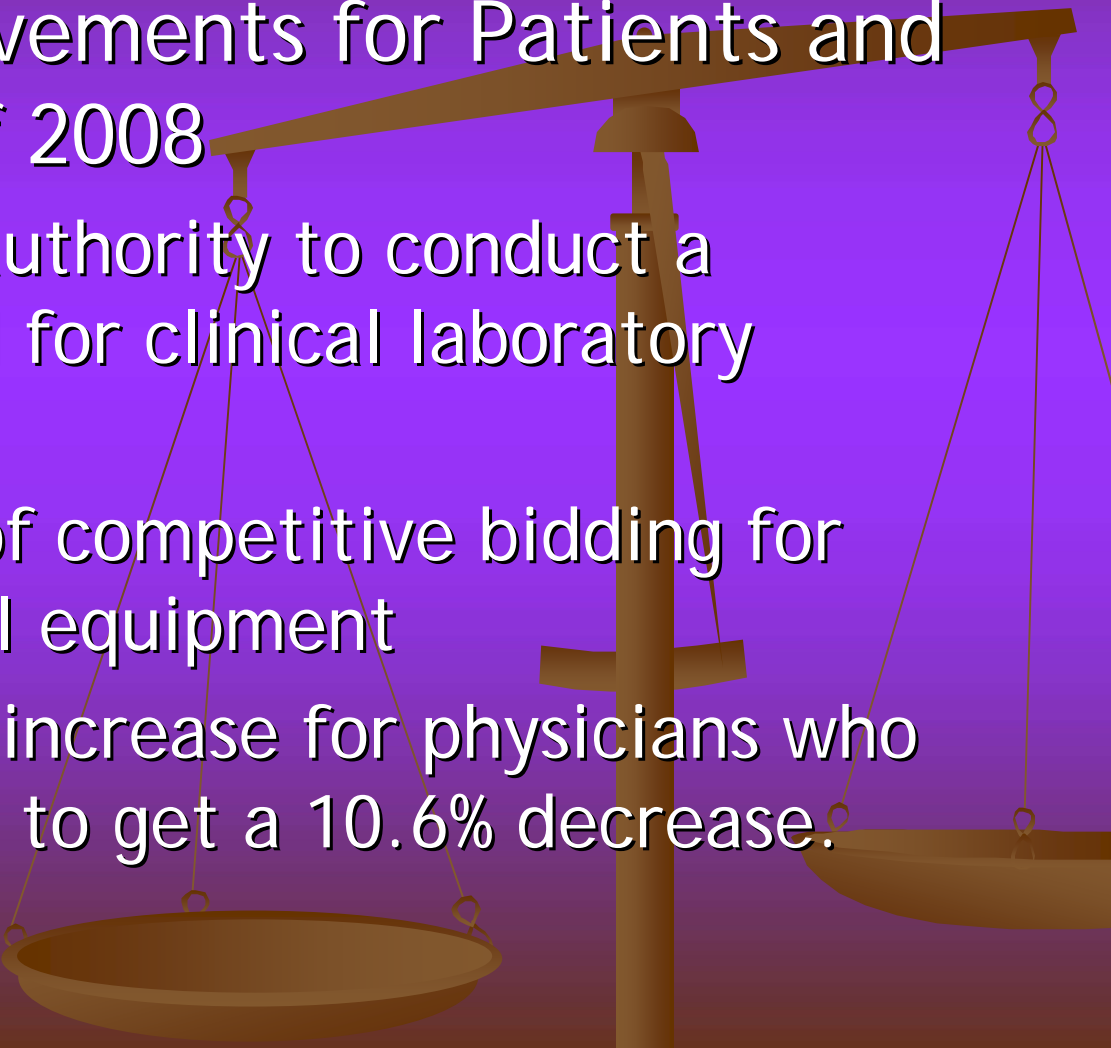


H.R. 1452

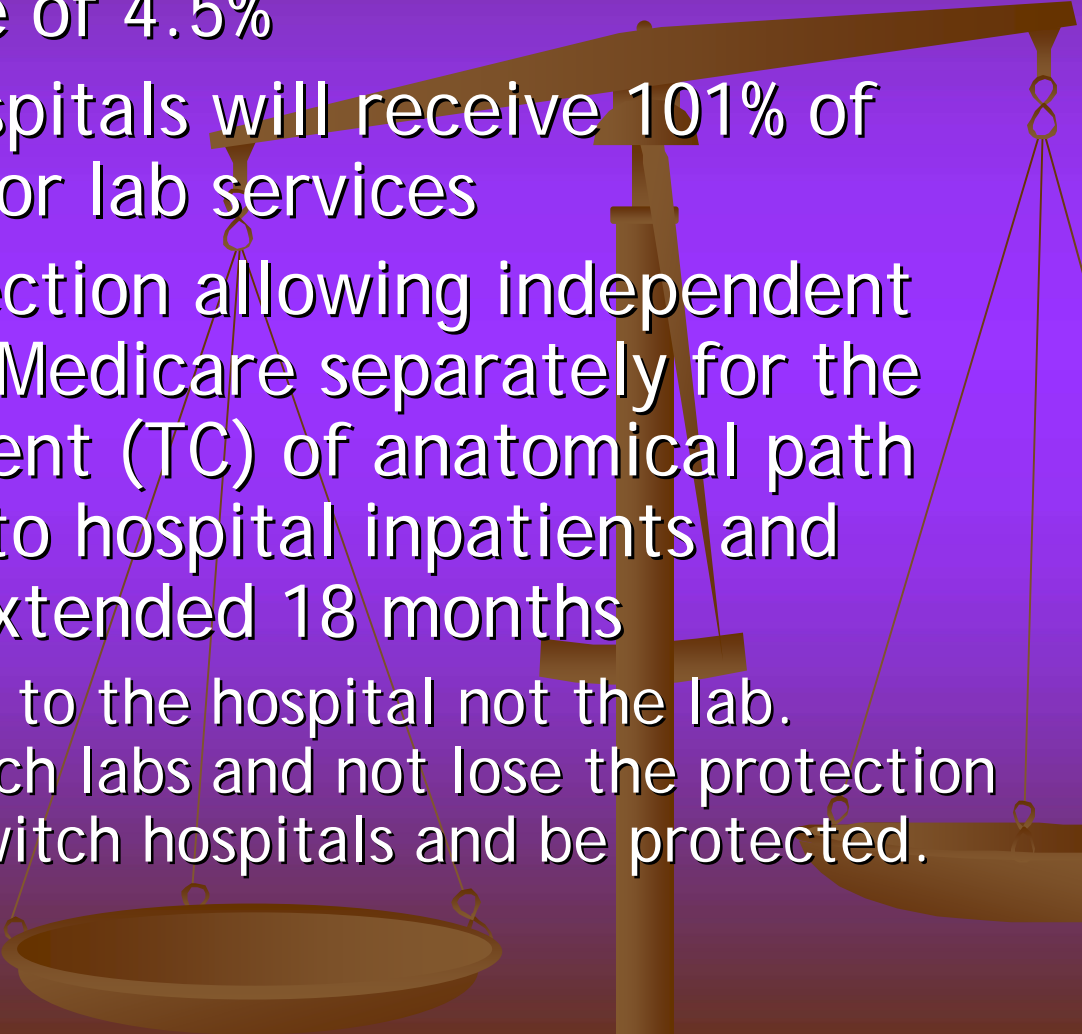
- Laboratory community not in complete agreement about this approach
- Many do not want to upset the status quo
- Others would prefer to work on new technology reimbursement only



NEW LAW

- Medicare Improvements for Patients and Providers Act of 2008
 - Repealed CMS authority to conduct a competitive bid for clinical laboratory services
 - Halted rollout of competitive bidding for durable medical equipment
 - Enacted a 0.5% increase for physicians who were scheduled to get a 10.6% decrease.
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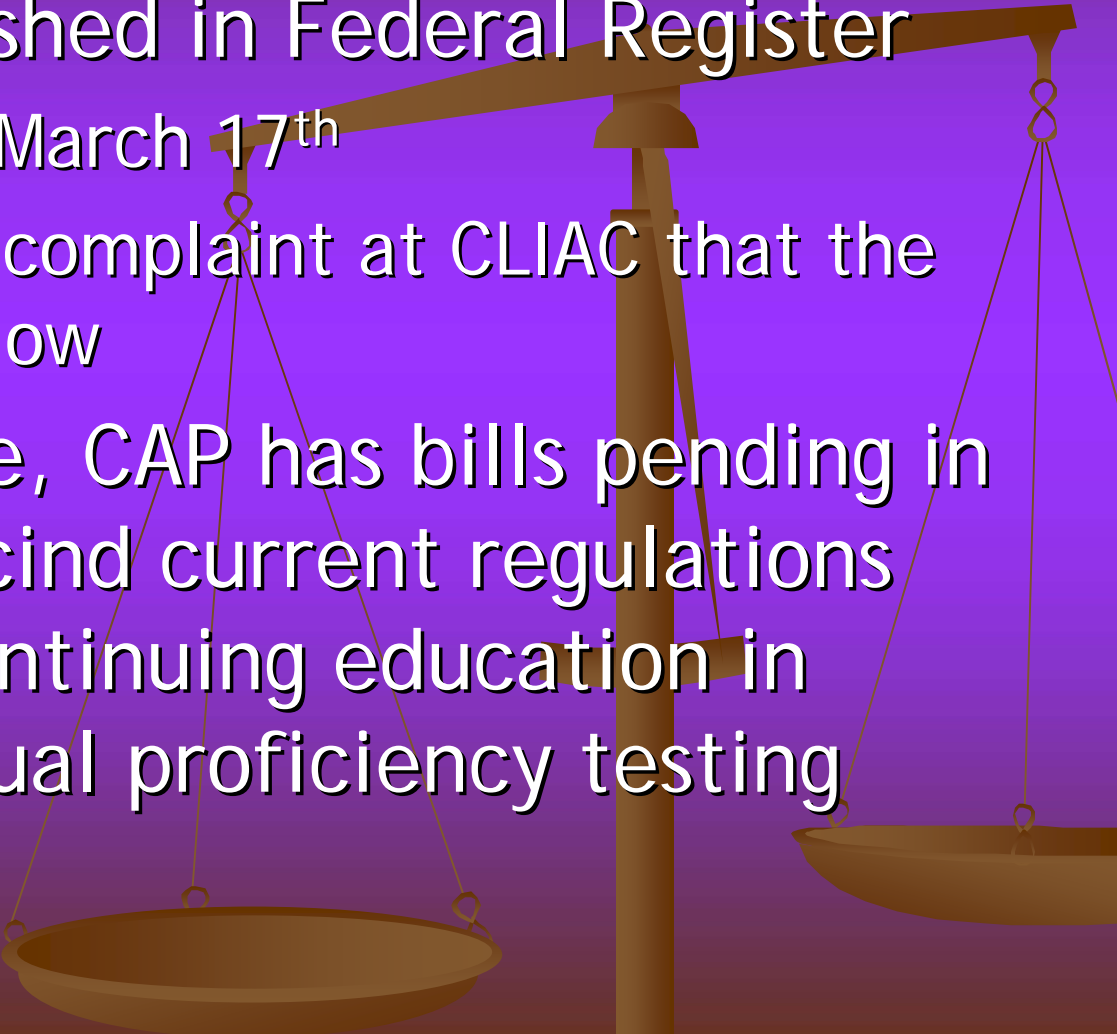
MIPPA 2008

- Laboratory update of 4.5%
 - Critical access hospitals will receive 101% of reasonable costs for lab services
 - Grandfather protection allowing independent labs to bill Part B Medicare separately for the technical component (TC) of anatomical path services supplied to hospital inpatients and outpatients was extended 18 months
 - Protection applies to the hospital not the lab. Hospitals can switch labs and not lose the protection but labs cannot switch hospitals and be protected.
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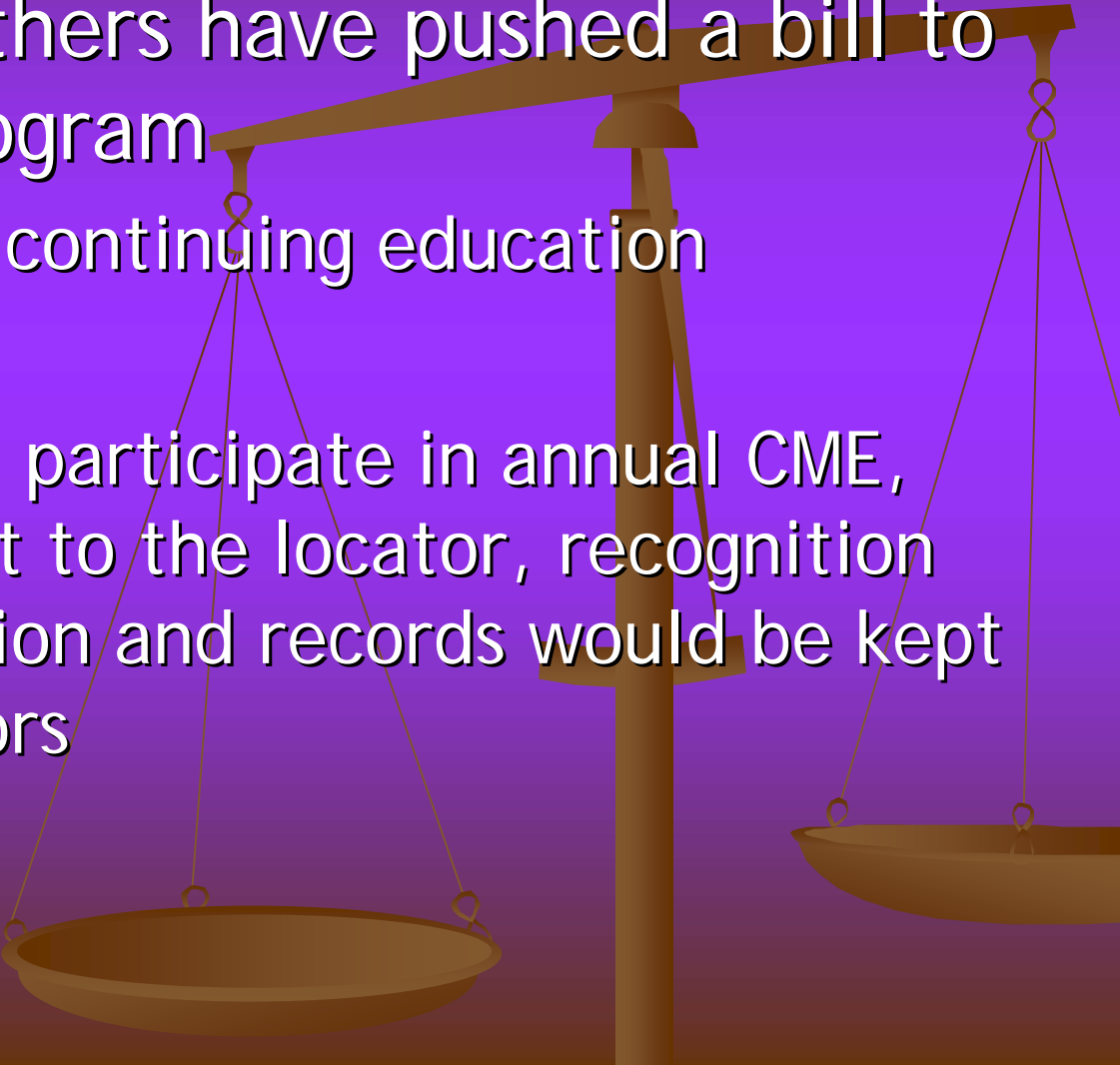
MIPPA 2008

- Expansion of Preventive Services Benefit
 - Under this law, Medicare no longer has to wait for an act of Congress to add coverage for a preventive service.
 - CMS can cover the service recommended by the US Preventive Services Task Force
 - Has to take the new service through the national coverage decision process
 - Welcome to Medicare physical modified to eliminate the deductible and extended coverage to a year after enrollment

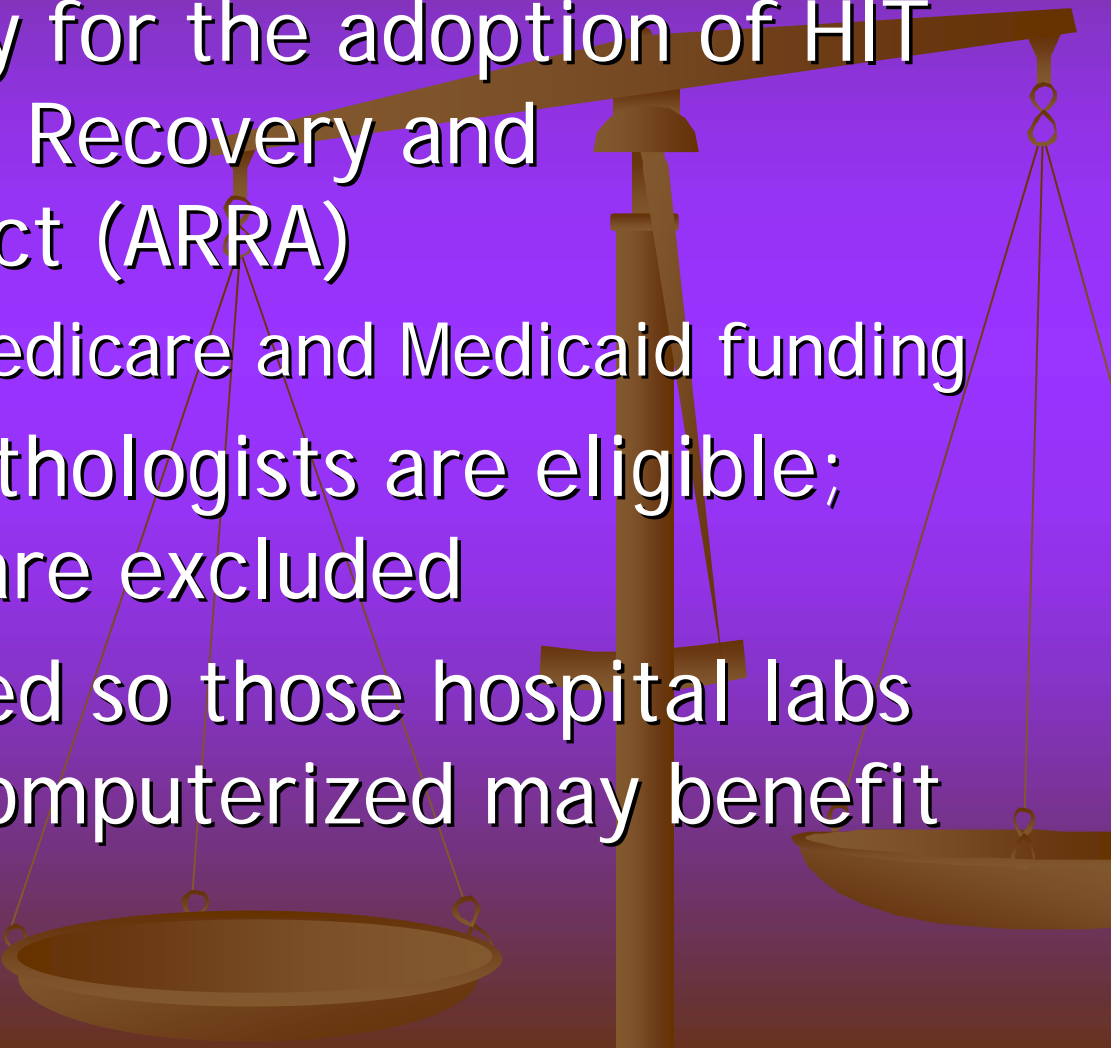
CYTOLOGY PROFICIENCY TESTING

- New rules published in Federal Register
 - Comments due March 17th
 - Cytotechs filed complaint at CLIAC that the process is too slow
 - In the meantime, CAP has bills pending in Congress to rescind current regulations and institute continuing education in place of individual proficiency testing
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CYTOLOGY PROFICIENCY

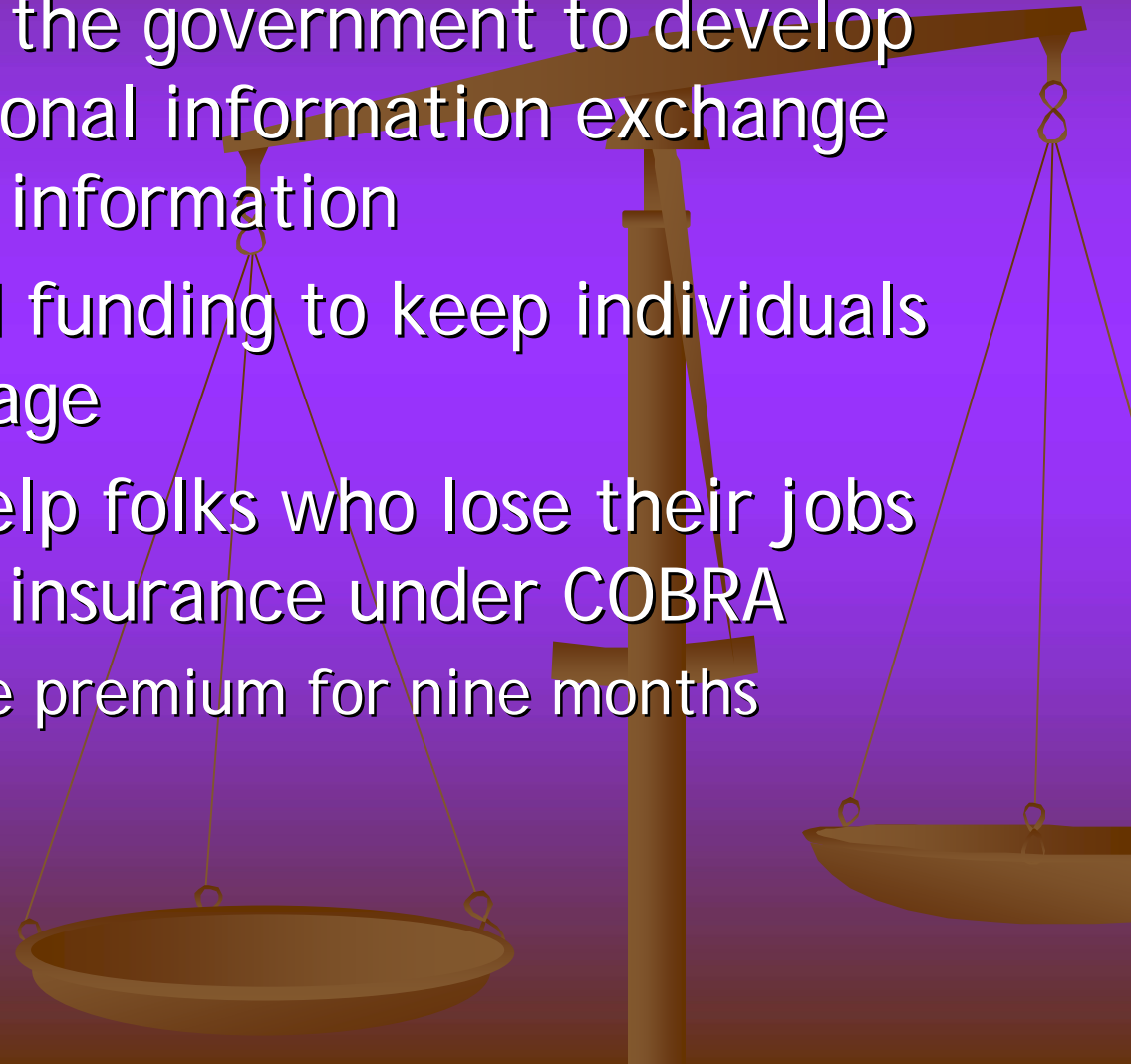
- ASC, CAP and others have pushed a bill to end the CMS program
 - Replace it with continuing education
 - S.2510
 - Everyone would participate in annual CME, that is pertinent to the locator, recognition and interpretation and records would be kept to show surveyors
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HEALTH INFORMATION TECHNOLOGY

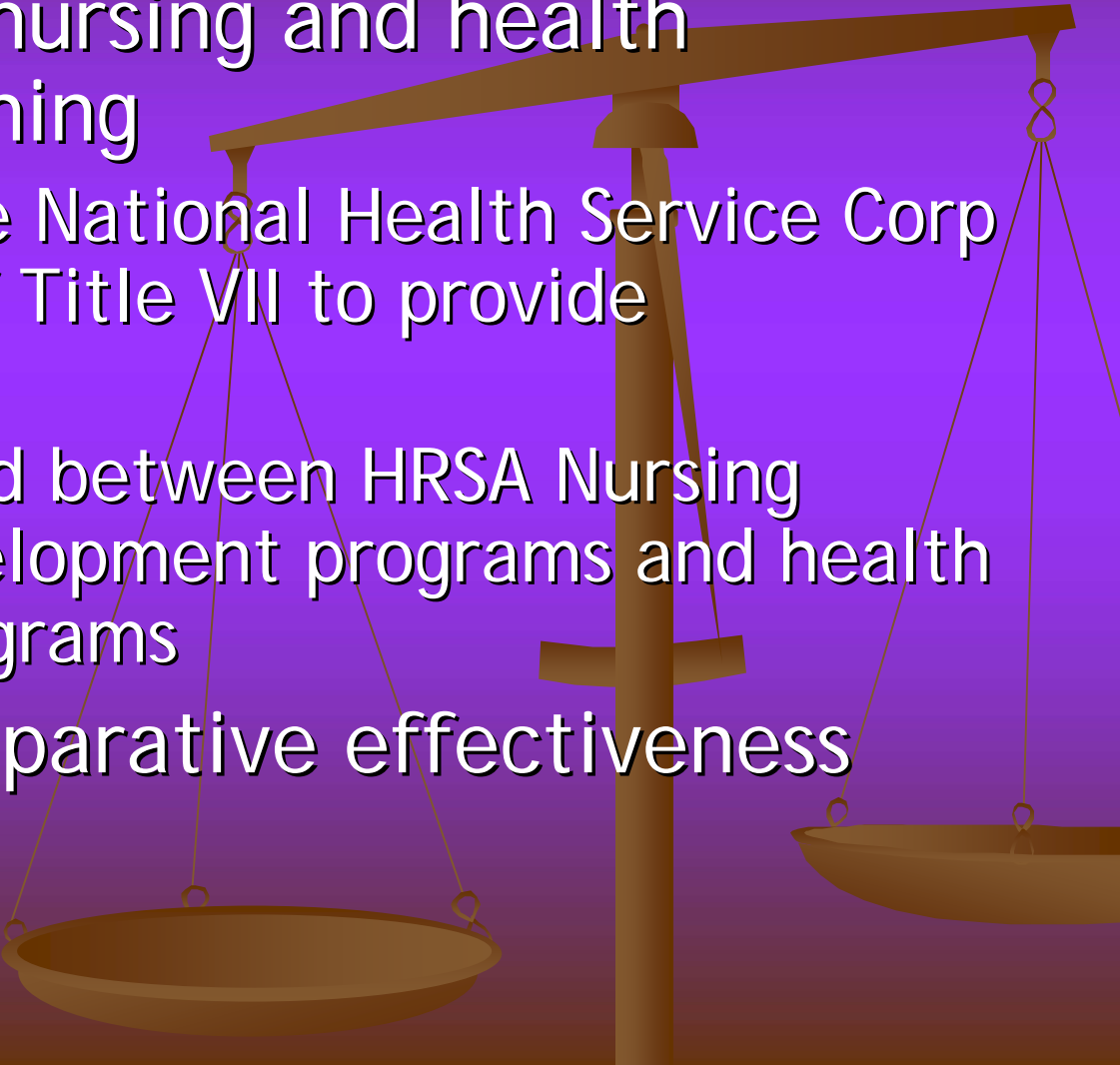
- Incentive money for the adoption of HIT in the American Recovery and Reinvestment Act (ARRA)
 - \$20 billion in Medicare and Medicaid funding
 - Independent pathologists are eligible; hospital based are excluded
 - Labs are included so those hospital labs who have not computerized may benefit
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ARRA 2009

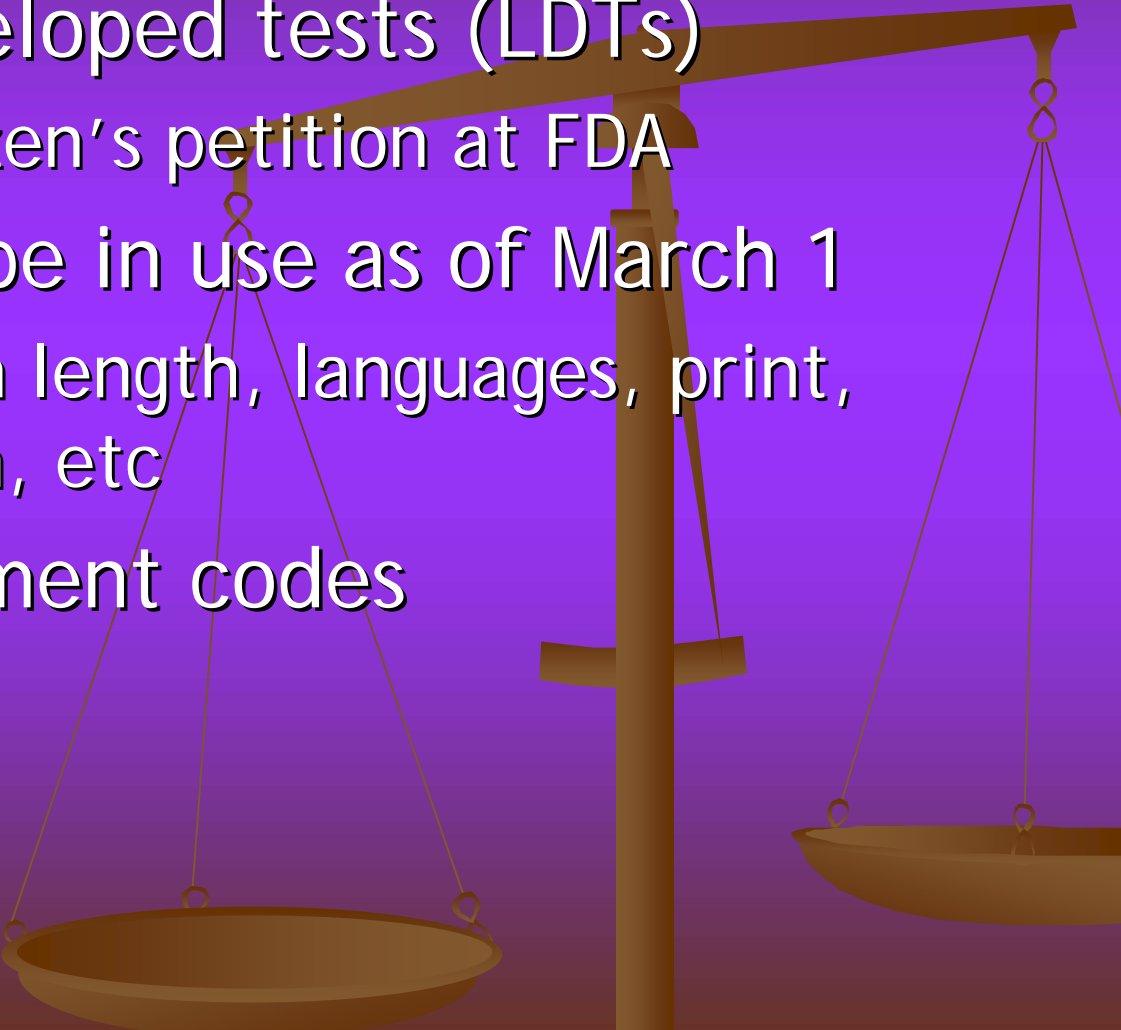
- Law also requires the government to develop standards for national information exchange and use of health information
- Provides Medicaid funding to keep individuals from losing coverage
- \$24.7 billion to help folks who lose their jobs keep their health insurance under COBRA
 - 65% subsidy of the premium for nine months



ARRA 2009

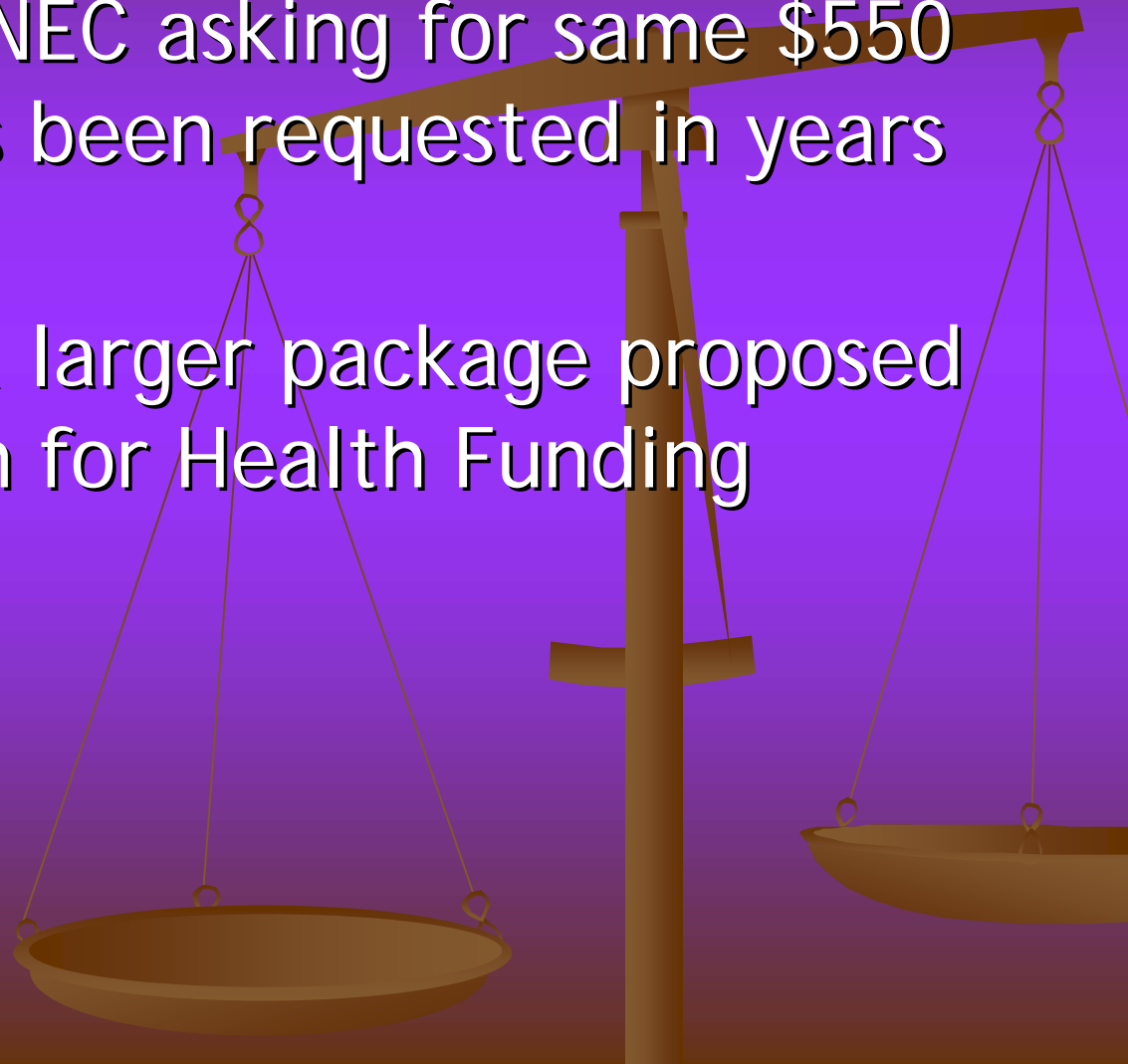
- \$500 million in nursing and health professions training
 - \$300 mil for the National Health Service Corp which is part of Title VII to provide scholarships
 - \$200 mil divided between HRSA Nursing Workforce Development programs and health professions programs
 - \$1.1 bil for comparative effectiveness research
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OTHER LAB ISSUES

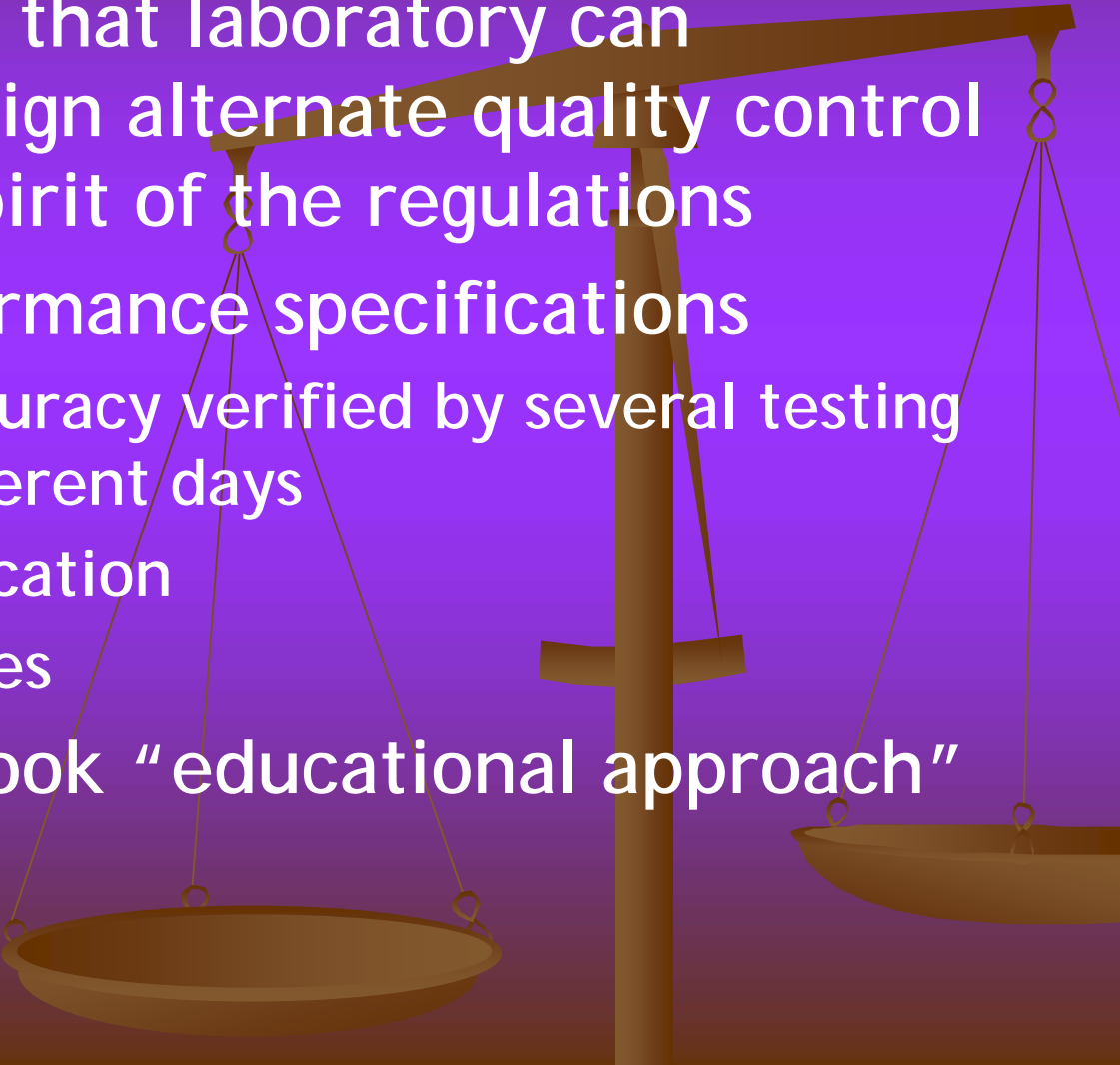
- Laboratory developed tests (LDTs)
 - Genentech citizen's petition at FDA
 - New ABN must be in use as of March 1
 - Very specific on length, languages, print, fonts, retention, etc
 - New reimbursement codes
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TITLE VII & VIII

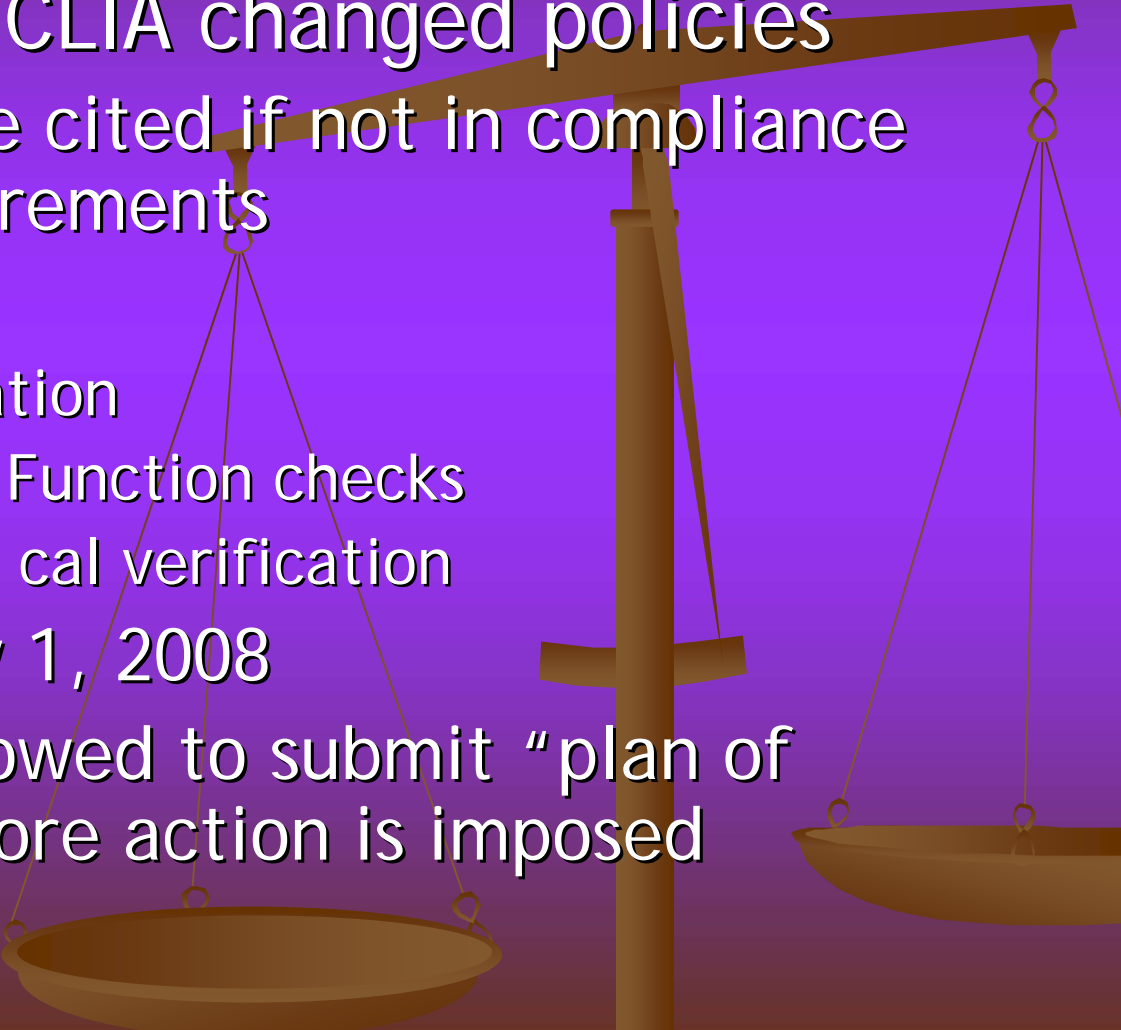
- For FY 2009 HPNEC asking for same \$550 million that has been requested in years past.
- This is part of a larger package proposed by the Coalition for Health Funding



CLIA REGULATIONS

- Guidelines stated that laboratory can interpret and design alternate quality control that meets the spirit of the regulations
 - Must verify performance specifications
 - Precision and accuracy verified by several testing personnel on different days
 - Calibration Verification
 - Control Procedures
 - CLIA inspectors took “educational approach”
- 

CLIA REGULATIONS

- In August 2007, CLIA changed policies
 - Now labs will be cited if not in compliance with 2003 requirements
 - Focusing on
 - Method verification
 - Maintenance & Function checks
 - Calibration and cal verification
 - Started January 1, 2008
 - Labs will be allowed to submit “plan of correction” before action is imposed
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CLIA REGULATIONS



- EQC still in guidelines - at least till CLSI finishes EP-22 and EP-23 and revises EP-18
 - JCAHO and COLA have options for QC that is similar to EQC
 - CAP has incorporated more flexibility into its guidelines for laboratories who want to reduce the use of external QC

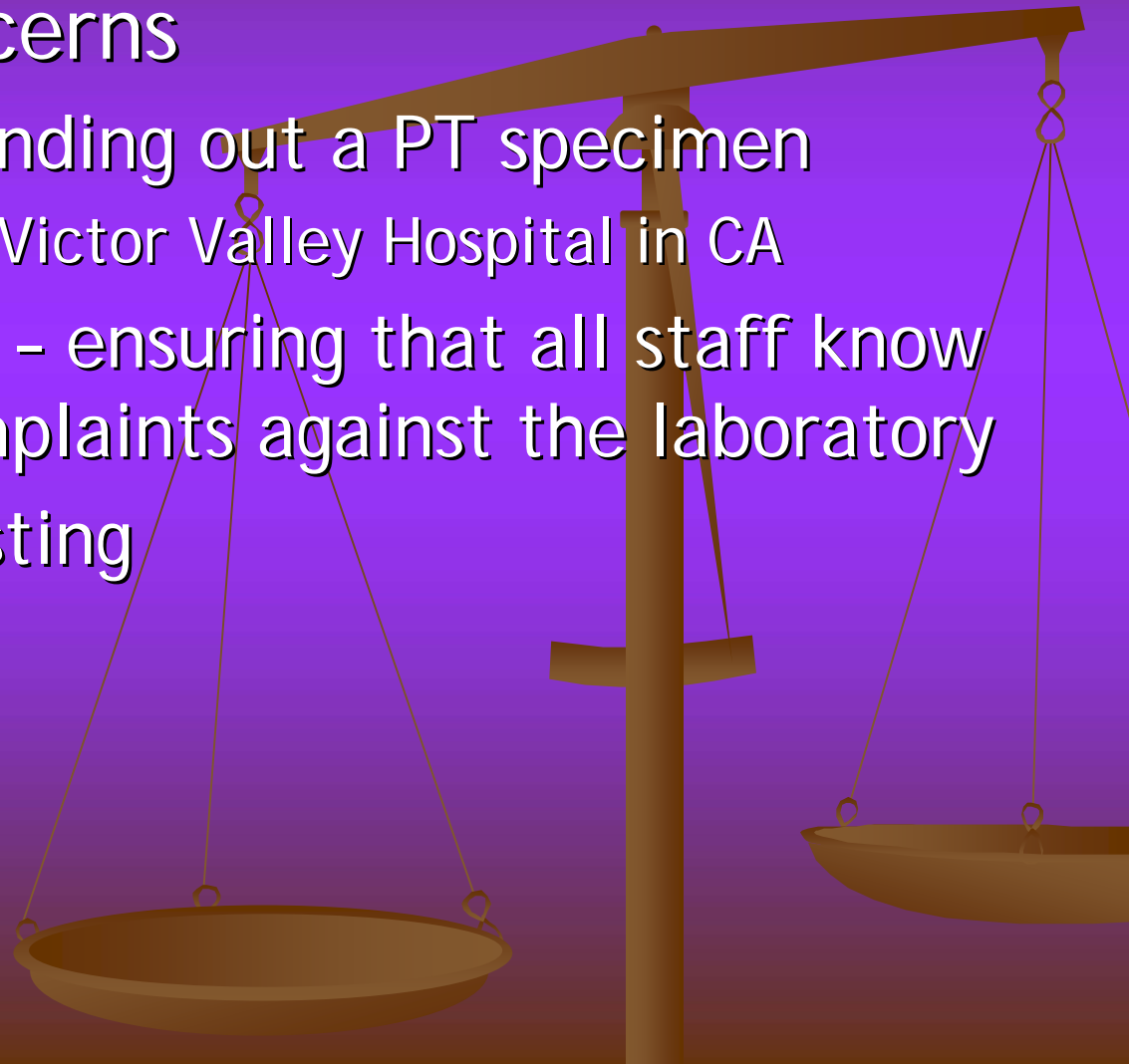
CLSI DOCUMENTS



- EP-18 - Quality Management for Unit-Use Testing: Approved Guideline for Quality Control Unit-Use Devices
- EP-22 - Presentation of Manufacturer's Risk Mitigation Information for Users of IVD Devices
- EP-23 - Laboratory Quality Control Based on Risk Management

CLIA REGULATIONS

- Other CLIA concerns
 - PT referral - sending out a PT specimen
 - Action against Victor Valley Hospital in CA
 - Whistleblowing - ensuring that all staff know how to file complaints against the laboratory
 - Cytology PT testing
 - Genetic testing



GENETIC TESTING



- The Secretary's (HHS) Advisory Committee on Genetics, Health & Society (SACGHS) issued a request for public comment about the oversight of genetic testing at <http://www4.od.nih.gov/oba/sacghs/FRnotice-OversightReport.pdf>
- Concerned about adequacy of CLIA regulations

SACGHS RECOMMENDATIONS



- In February, the Committee finalized its recommendations addressing
 - How to determine analytic and clinical validity as well as clinical utility
 - What distinguishes genetic tests from all other laboratory tests for oversight purposes
 - Who should be responsible for these issues
 - What resources are needed for PT testing?
What is currently available?

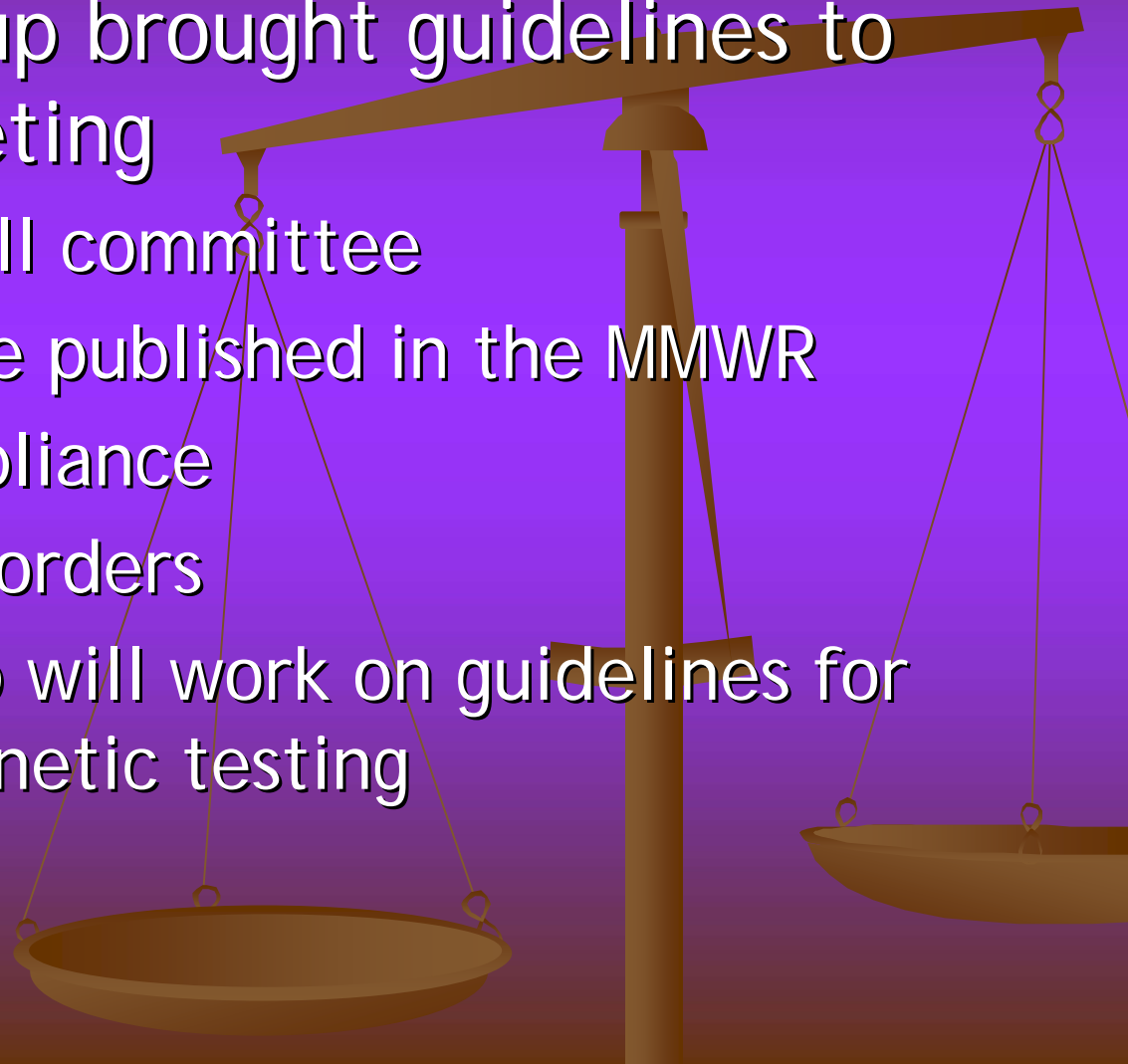
SACGHS RECOMMENDATIONS



- The shock was that on FDA's urging, the word "genetic" was removed from the document
- Therefore the recommendations would apply to all laboratory tests
- Committee has not released final document
- We will post information as we receive it

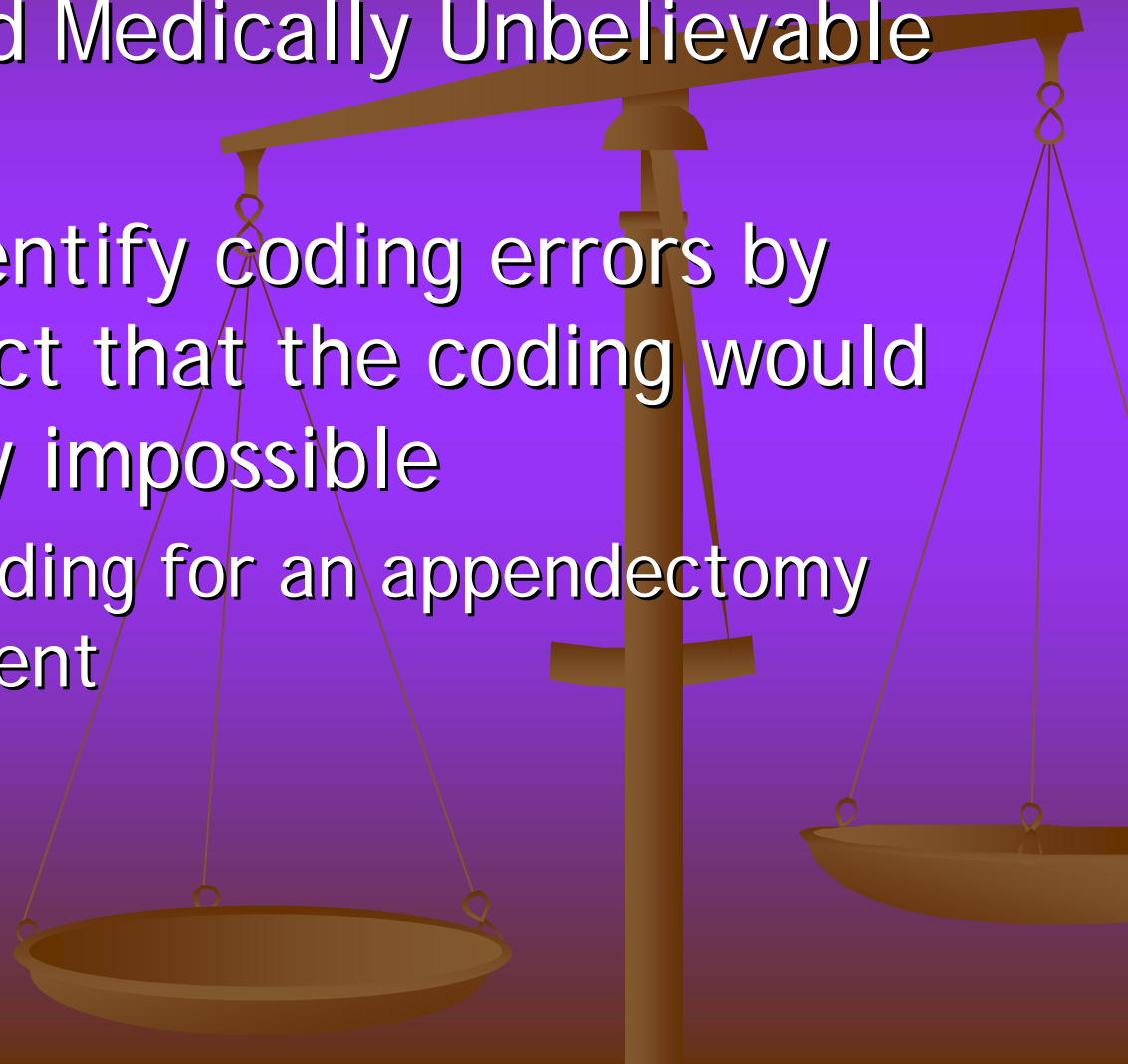
CLIAC GENETICS

- CLIAC Workgroup brought guidelines to September meeting
 - Approved by full committee
 - Scheduled to be published in the MMWR
 - Voluntary compliance
 - For somatic disorders
 - New workgroup will work on guidelines for biochemical genetic testing



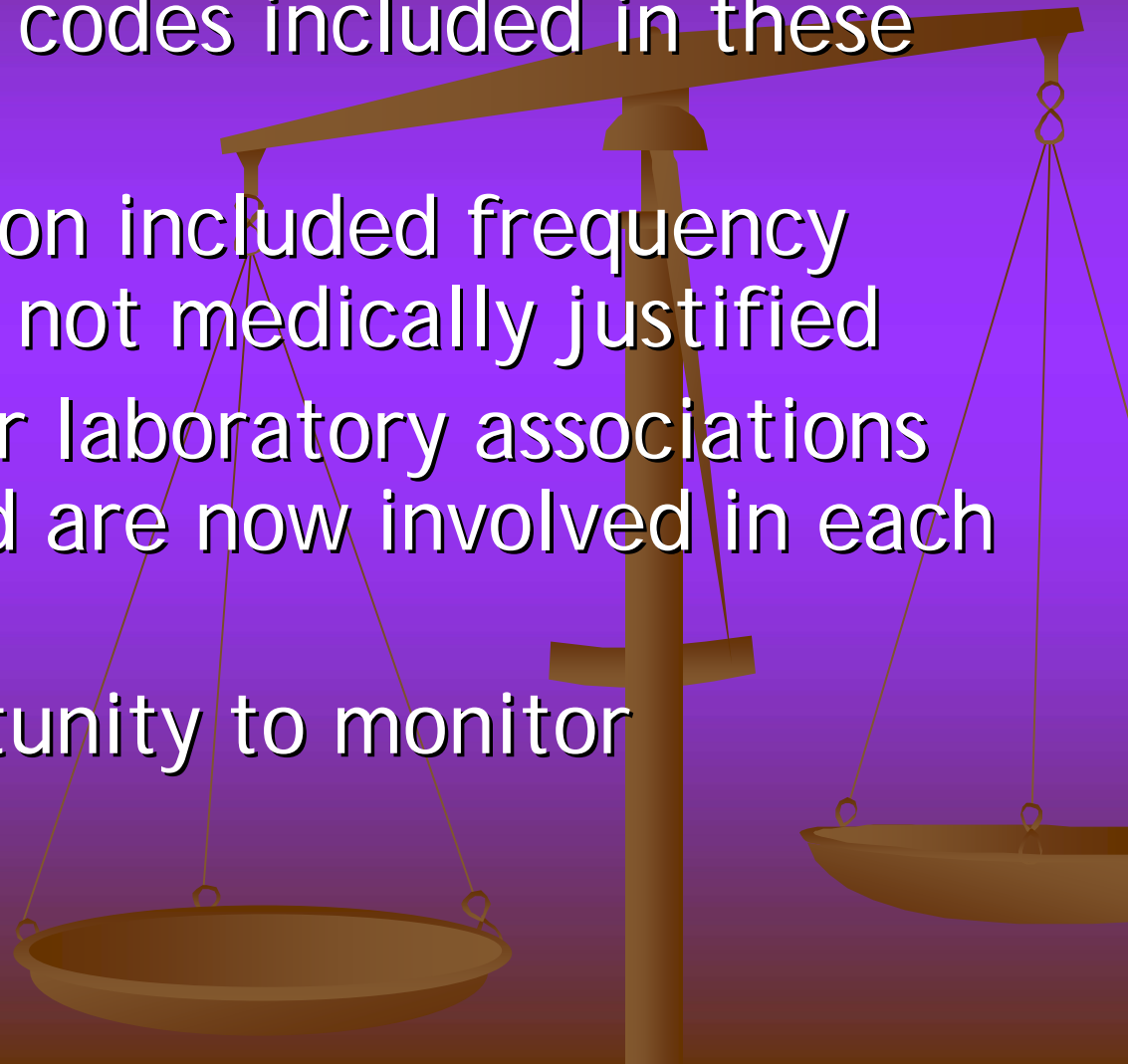
MEDICALLY UNLIKELY EDITS

- Originally called Medically Unbelievable Edits
- Supposed to identify coding errors by virtue of the fact that the coding would be anatomically impossible
 - For instance coding for an appendectomy twice on a patient

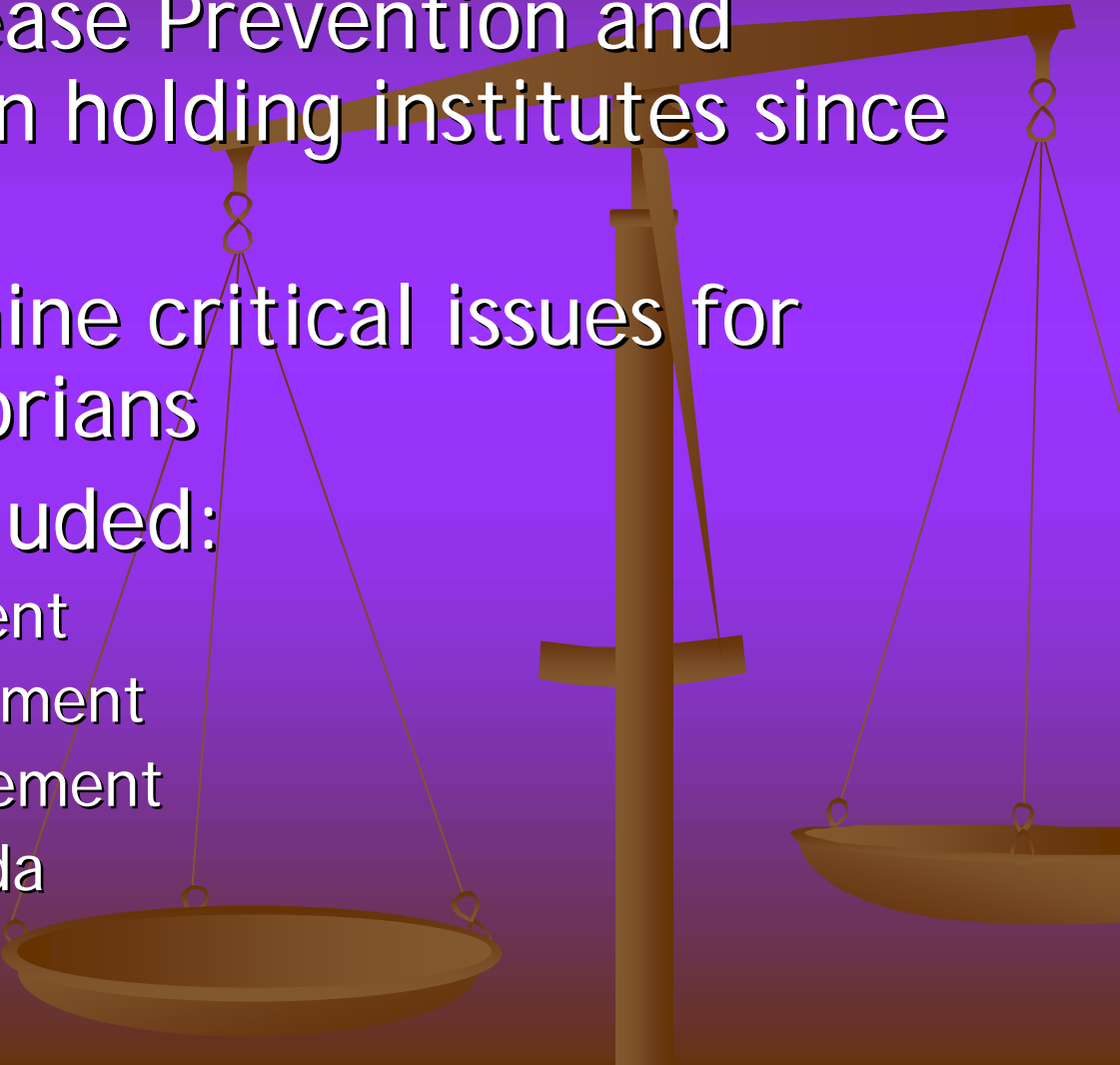


MEDICALLY UNLIKELY EDITS

- Laboratory CPT codes included in these edits.
- The first iteration included frequency edits that were not medically justified
- ASCLS and other laboratory associations commented and are now involved in each phase of edits
- Again an opportunity to monitor utilization

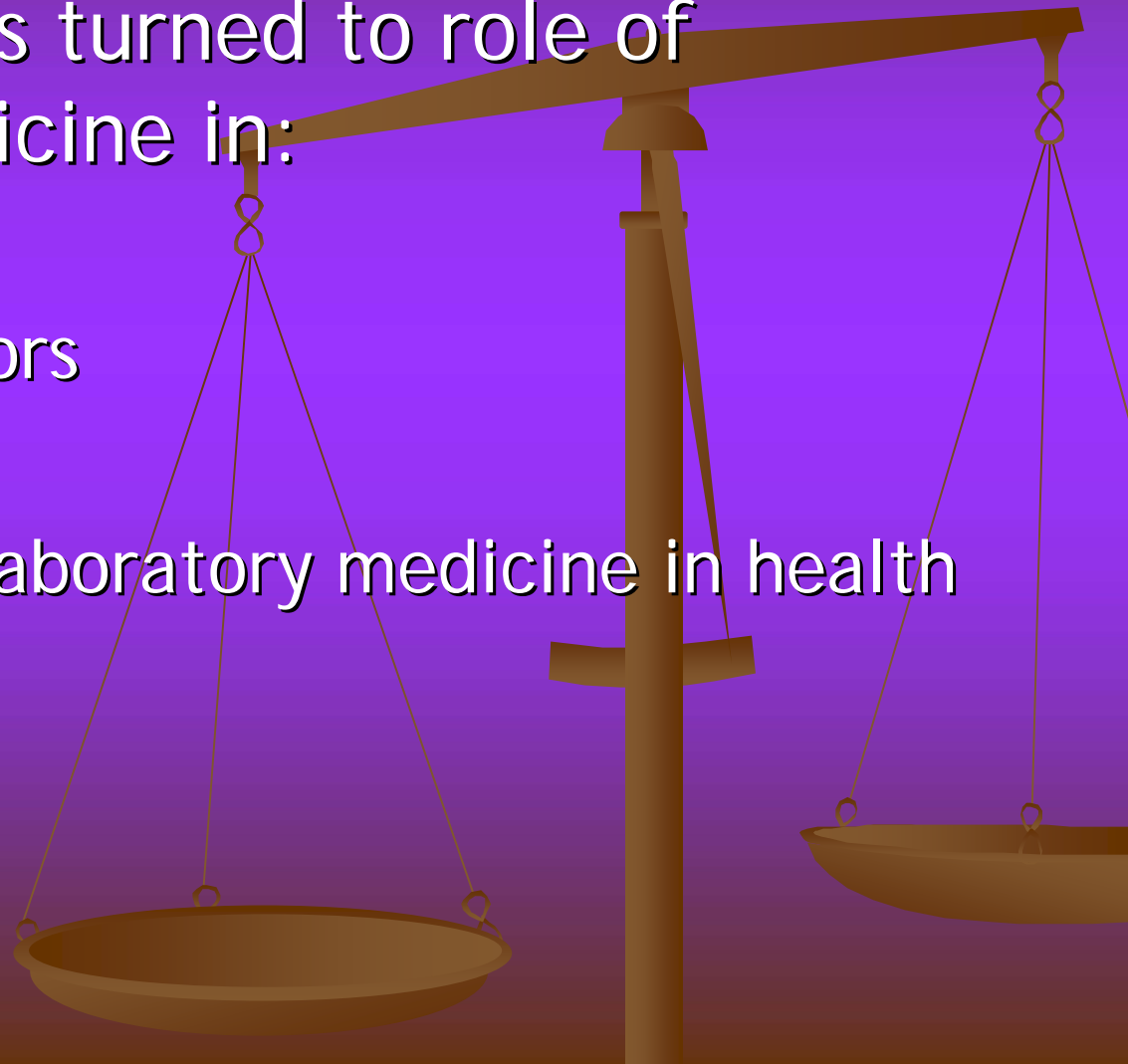


CDC INSTITUTES

- Centers for Disease Prevention and Control has been holding institutes since 1984
 - Forums to examine critical issues for clinical laboratorians
 - Topics have included:
 - Cost Containment
 - Quality Management
 - Quality Improvement
 - Research Agenda
- 

CDC INSTITUTES

- From 2003 focus turned to role of laboratory medicine in:
 - Patient safety
 - Quality indicators
 - Best Practices
 - Integration of laboratory medicine in health care



CDC INSTITUTE 2007

- Critical Issues in Laboratory Medicine:
Managing for Better Health
- Workgroups
 - Advancing Collaboration
 - Measuring Quality
 - Preparing for the Future



CDC INSTITUTE 2007

■ Purpose:

- Identify what is needed to better integrate laboratory services into the health care/wellness continuum of individuals.
- Achieve more efficient and cost effective care
- Accomplished through better communication and collaboration with all care givers and consumers of health and health care.



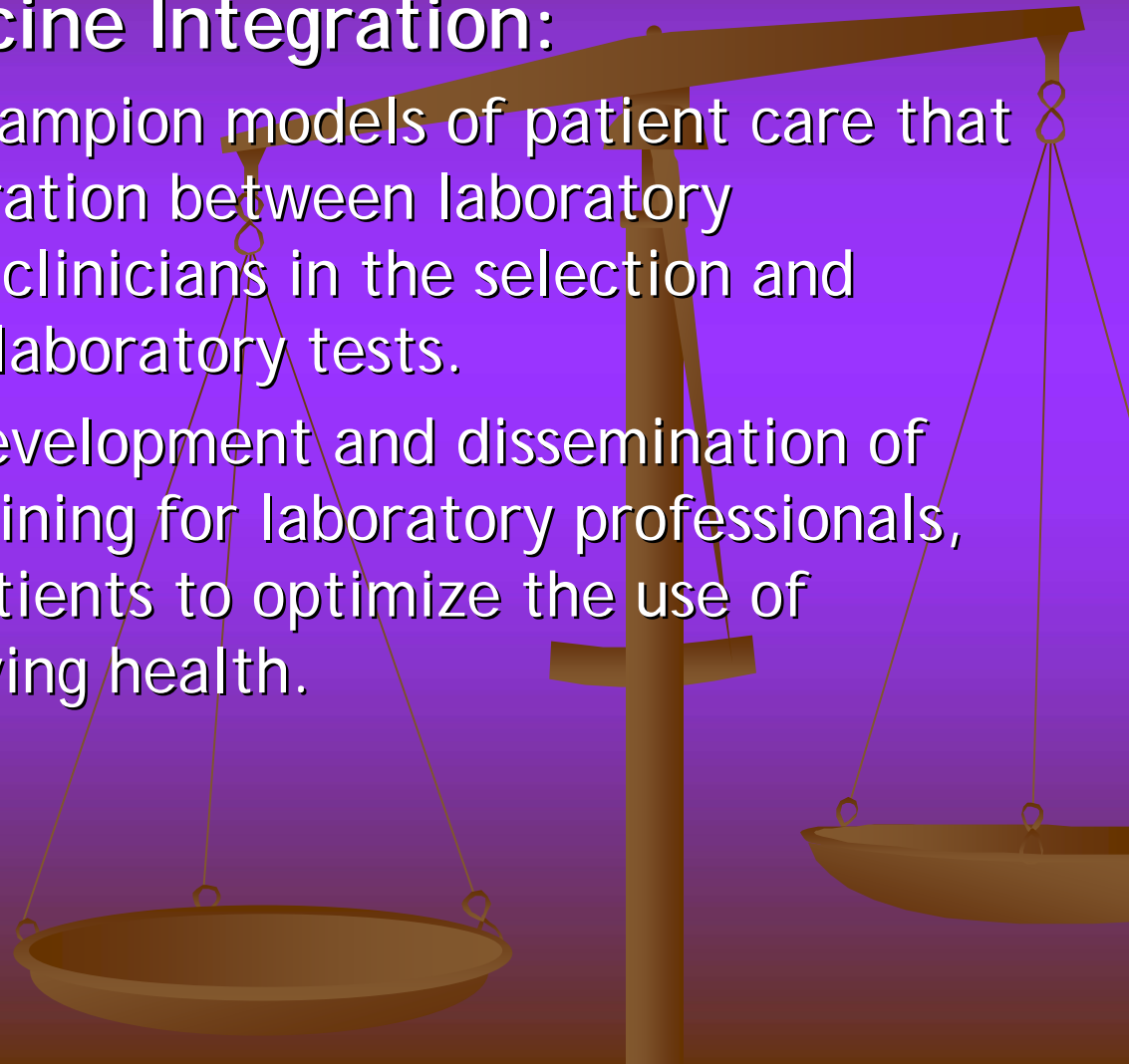
INSTITUTE FOLLOW-UP



- The Institute Committee identified action steps that will be the focus of work moving forward:
 - Evidence-base/Framework: Develop a framework(s) with which to review, catalogue, and create evidence-based measures and practices in laboratory medicine that emphasize the added value of these services and produce quality patient outcomes

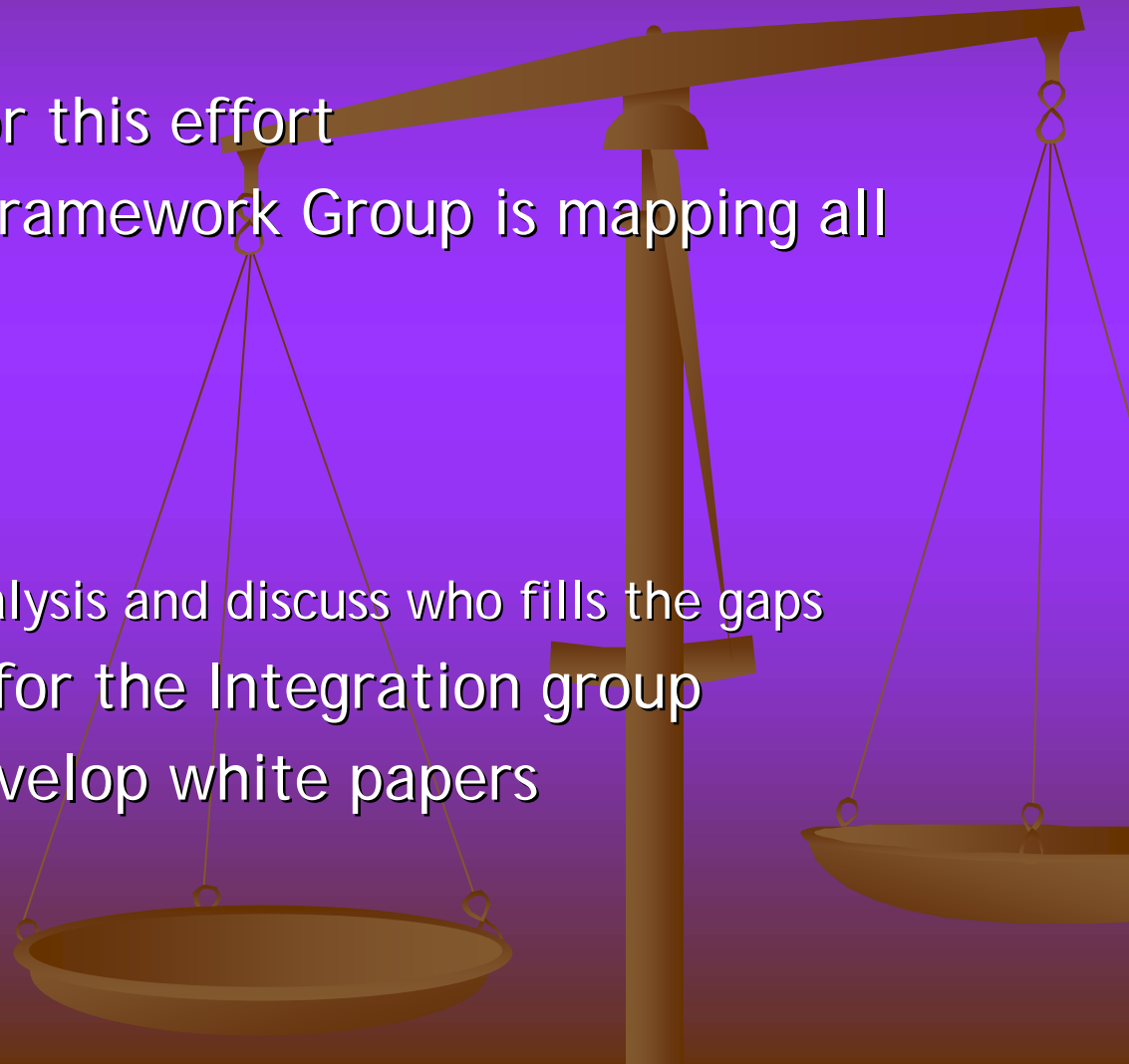
INSTITUTE FOLLOW-UP

- **Laboratory/Medicine Integration:**
 - 1. Identify and champion models of patient care that facilitate collaboration between laboratory professionals and clinicians in the selection and interpretation of laboratory tests.
 - 2. Promote the development and dissemination of education and training for laboratory professionals, clinicians, and patients to optimize the use of testing for improving health.



INSTITUTE FOLLOW-UP

- Current activity:
 - Finding a home for this effort
 - Evidence Based/Framework Group is mapping all similar efforts
 - AHRO
 - NQF
 - CDC Contracts
 - Develop a gap analysis and discuss who fills the gaps
 - Assembling team for the Integration group
 - Both groups to develop white papers



GRASSROOTS ADVOCACY

- In public policy and legislative arenas, each one of us is a grassroots member
- The most effective way to get any of our messages across
- Individuals expressing their opinion to the people we put in office
- We need your help

