

Legislative & Regulatory Issues Facing Pathology & Laboratory Medicine

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Learning Objectives

1. Describe the key elements of the *Patient Protection and Affordable Care Act of 2010* which will affect our specialty.
2. Describe other governmental initiatives of real or potential importance.
3. Discuss how political advocacy activities can influence these decisions.

The Patient Protection and Affordable Care Act of 2010 (PPACA) and Health Care and Education Reconciliation Act of 2010 Titles

- Quality, affordable health care for more Americans
- Role of public programs: expanding Medicaid & CHIP enrollment
- Improving the quality and efficiency of health care
- Prevention of chronic disease & improving health
- Health care workforce
- Transparency & federal program integrity
- Improving access to innovative medical therapies
- Community Living Assistance Services and Support (CLASS)
- Revenue provisions for funding and to potentially reduce health care expenditures

Health Care.gov

- <http://www.healthcare.gov/> opened July 2010
 - “Take health care into your own hands”
 - **Find Insurance Options**
 - See which public, private and community programs meet your needs
 - **Learn About Prevention**
 - Live well. Learn how.
 - **Compare Care Quality**
 - Hospital Compare
 - **Understand the New Law**
 - **Information for You**
 - By category of demographics (individuals, families, seniors, etc.)

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PPACA provisions that will affect labs and pathology practices

- Updates to the Medicare Clinical Laboratory Fee Schedule (CLFS)
- Technical Component of Certain Physician Pathology Services
- Preventative health services promotion
- Molecular diagnostics test demonstration project
- Payment systems for new lab tests
- National pilot program on payment bundling
- Independent Payment Advisory Board
- Comparative Effectiveness Research
- Insurance reforms
- Medical devices excise tax
- Transparency & program integrity provisions

CLFS Updates

- The CLFS is updated annually based upon the CPI, unless Congress acts otherwise...
 - 2011 and beyond:
 - Productivity adjustments (est. 1.1-1.3% annual spending reductions)
 - Cannot reduce the update below 0%
 - 2011-2015:
 - 1.75% cut in the annual CPI update
 - Can result in an update $<0\%$
 - **June 2010 CPI = 1.1%**
 - Therefore, 1.1% minus $\sim 1.3\%$ = 0% floor
 - 0% minus 1.75% = **-1.75% CLFS update for 2011**

Impact: Pricing and reimbursement pressures will continue.

Technical Component of Certain Physician Pathology Services

- The so-called “TC Grandfather Clause”
 - Continues to permit independent laboratories to receive direct Medicare payments for pathology technical services to certain in-patients
 - Expires December 31, 2010

Impact: Unless extended, this will affect certain existing arrangements, especially in rural communities and require independent labs to bill hospitals directly

Promoting Preventative Health Services

- Requires expanded coverage for certain preventative health services (**45 services**), including **lab tests (23)**
- Eliminates the cost-sharing (co-payment) for those services rated by the US Preventative Services Task Force (USPSTF)
- Requires the USPSTF to broaden its representation by seeking recommendations for expanded preventative services from a number of recognized expert organizations
- Public awareness campaign

Impact: Unpredictable increase in demand for laboratory services

Molecular Diagnostics Test Demonstration

- Two-year, \$100 million demonstration project
- Applies to tests that “analyze gene protein expression, topographic genotyping or cancer chemotherapy sensitivity assays”
- Determine alternative payment rates for these tests
- Report to Congress within two years on the impact on access, quality, health outcomes and expenditures
- Begins July 2011
- Affects hospital-based and independent labs

Impact: Uncertain at this time.

Payment System for New Lab Tests

- Convene a public meeting on how to determine payment levels for new tests paid under Medicare
- Report to Congress on the findings and any recommendations for necessary legislative or regulatory action

Impact: Uncertain at this time.

National Pilot Program on Payment Bundling

- A national voluntary, pilot program to coordinate care during an entire episode of care
 - Part A and Part B services, but not Part C
 - Hospital in-patient and out-patient services
 - Physician in-patient and out-patient services
 - ED visits
 - Hospital readmission services
 - Home health, SNF, rehabilitation & long term care services
- DHHS to establish no later than January 1, 2013
- Expandable after January 1, 2016
- Test bundled payment arrangements for all services

Impact: This pilot program will include laboratory & pathologist services, with uncertain impact.

Independent Payment Advisory Board

- Creates a 15 member advisory board on Medicare payments
- 2014 and beyond:
 - If spending exceeds a target growth rate, spending reductions are recommended
 - Congress must pass by super-majority vote an alternative, equally effective, proposal or the IPAB proposal becomes law
 - Hospitals exempt until 2020
 - Submit advisory report in those years not requiring spending reduction recommendations
 - Make recommendations every two years on how to reduce spending of private health care

Impact: Shifts the responsibility for payment policy from Congress to an unelected board of the Executive Branch.

Comparative Effectiveness Research (CER)

- Quality care (IOM definition) = safe, timely, efficient, effective, equitable and patient-centered
- **Goal of CER** = evaluating alternative interventions (therapeutics, medical/surgical, medical devices, labs, biotech, etc.) for differences in benefit, harm, outcome and/or cost
- The American Recovery & Reinvestment Act of 2009 appropriated \$1.1B for CER, over two years
- The PPACA of 2010 creates the *Patient-Centered Outcomes Research Institute* to oversee CER funding
- The Institute for Medicine has recommended a portfolio of 100 study topics for CER

Impact: The challenge for pathology & laboratory medicine is to assess the ability to establish causal connections between tests and outcomes (clinical utility), including in personalized medicine

Insurance Reforms

- A variety of near-term and long-term insurance coverage reforms aimed at extending coverage and reducing the number of uninsured
- Demonstrations of new delivery models (e.g., medical home, accountable care organizations, etc.)

Impact: Unpredictable but likely increase in the demand for pathology and laboratory services as more people are insured; uncertainty with new delivery models.

New Delivery and Payment Systems: Accountable Care Organizations (ACO)

- The *PPACA* includes new patient care models to encourage new delivery and payment structures based upon patient outcomes and mutual accountabilities, such as:
 - Accountable Care Organizations (ACO)
 - Patient Centered Medical Home (PCMH)
- ACO defined:
 - “groups of **providers** that have the **legal structure** to **receive and distribute payments** to **participating providers**, to provide **care coordination**, to invest in infrastructure and **redesign care processes**, and to **reward high quality and efficient services**”
 - Source: “*Implementing Accountable Care Organizations*,” Berkeley Center on Health, Economic & Family Security, Policy Brief, May 2010; www.law.berkeley.edu/chefs.htm

Medical Device Excise Tax

- Part of the White House “deal” with certain provider groups to help fund the *PPACA*.
- 2.3% tax on the “first sale” for use of medical devices, beginning in 2013
 - Includes reagents and kits sold to clinical laboratories
 - IVD manufacturers pay the tax

Impact: Cost passed on to customers.

Uncertain whether Laboratory Developed Tests are also subject to the tax.

Transparency & Program Integrity Provisions

- Physician “Sunshine” requirements
 - Drug and device manufacturers must provide annual reports to DHHS
 - **For provision of a payment or other transfer of value to a covered recipient (including physicians)**
 - Cash or cash equivalent (including consulting fees, honoraria, food, travel, charitable contribution, direct compensation for speaking, grants, etc.)
 - Stock or stock options, & any ownership interest
 - Dividend, profit or other ROI
 - ***Any form of payment or other transfer of value***

Impact: Uncertain whether these includes labs as “manufacturers,” but does include any physician/faculty member paid by a covered manufacturer.

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Medicare Physician Fee Schedule (PFS) Updates

- Payments to physicians are updated annually by CMS
 - Since 1997, the ***Sustainable Growth Rate*** formula is used to adjust fees based upon actual spending compared to target spending
 - **A 21% cut was programmed for 2010**
- An act of Congress is required to modify the SGR update (“Kicking the can down the road”)
 - ***The Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010*** (H.R. 3962) included a temporary fix of a **2.2% update** from June 1 through November 30, 2010 (**December 1 = ~23% cut**)
- The proposed legislative “fix” to the SGR would cost up to >\$260 billion over 10 years (CBO estimate)

Impact: Failure to extend or “fix” the SGR may result in significant numbers of physicians dropping Medicare patients.

2011 Medicare PFS Proposed Rule

- Issued by CMS June 25, 2010
 - Proposed update to the PFS Conversion Factor
 - An estimated **27% negative** update for CY2011
 - **Current CF = \$36.8728; Proposed CF = \$26.6574**
 - Expiration of the payment for TC of Certain Physician Pathology Services (the “Grandfather” clause) December 31, 2010
 - Productive Adjustment for the CLFS
 - Physician signatures on requisitions for clinical laboratory and physician services
 - Disclosure requirements for In-Office Ancillary Services
Exception for Certain Imaging Services
 - **No specific proposals for anatomic pathology services.**

Molecular Test Coding

- Only method-specific codes currently exist (*CPT* 83890-83915)
 - Lack specificity and granularity for clinical conditions (e.g., genetic disorders)
 - Lack of coverage by many insurers
 - Miss-valued reimbursement rates
 - **And, PhD geneticists cannot bill for their services (non-physicians)**
- AMA CPT Editorial Panel MoPath Working Group is fast-tracking a new coding proposal
 - Does not address the reimbursement issue

Laboratory Developed Tests and FDA Oversight

- High complexity labs are subject to CLIA requirements for test validation
- In vitro diagnostics manufacturers (IVD) are subject to FDA approval as “medical device” manufacturers
- FDA believes that LDT’s are medical devices subject to their jurisdiction
 - Exercise “enforcement discretion”
 - Draft IVDMIA Guidance Document and multiplex ASR’s
 - Public Meeting, July 19-20, 2010
- Legislative and regulatory pathways for reconciliation exist
 - O. Hatch (R-UT): *The BETTER Act*

Impact: Fears that onerous FDA oversight of LDT’s will stifle innovation and impede rapid access to new diagnostics.

FDA/CDRH Public Meeting on LDT oversight

- Key take away messages:
 - FDA was there to listen (but very likely have a pre-conceived notion of their responsible pathway)
 - LDTs provide value, especially for unmet medical needs
 - There is a need for a risk-based approach to LDT oversight
 - There is a need for an LDT public registry
 - There is a need for standards in LDT validation
 - There should be a third party process for validating LDT clinical validity/utility (“intended use”) claims
 - Any new framework should be adaptable
 - The best of CLIA and FDA oversight should be combined
 - Innovation cannot be stifled and “orphan” disease testing needs special attention
- Next step(s)
 - FDA will likely respond with Draft Guidance(s) on LDTs

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Political Advocacy

- Why get involved?
- How to get involved:
 - As an individual
 - Dr Navin's story
 - Political Action Committees (PAC)
 - As an organization
 - Hiring your own consultants
 - Through other organizations
 - Professional societies (CLMA, CAP, ASCP)
 - Trade associations (ACLA)

Questions?

Accountable Care Organizations

- Delivery models that may qualify:
 - Integrated Delivery System (IDS)
 - Multi-Specialty Group Practice (MSGP)
 - Physician-Hospital Organization (PHO)
 - Independent Practice Association (IPA)
- Goals include:
 - Incentive to keep patients healthy
 - Prevent disease and disability
 - Coordinate comprehensive chronic care management
- Payments based upon health outcomes
 - Progression from fee-for-service, to bundled and episode-of-care payments, to capitation as ACO mature

Obstacles to ACO Implementation

- Federal anti-trust law prohibiting anti-competitive behavior
- State corporate practice of medicine statutes
- Federal anti-kickback statute that prohibits payments in exchange for referrals of services under Federal plans
- Federal Stark law which governs physician self-referral
- Federal civil monetary penalties law that govern false claims
- Changing the delivery paradigm from individual provider case management to team-oriented case management
- Linking patient outcomes to financial incentives
- Access to “how to” technical assistance resources, including the adoption of electronic health records

The BETTER Bill

EMR Donations

- Electronic medical record systems are becoming increasingly popular, especially in physician offices
- The *HITECH Act of 2009* provides financial incentives (up to \$44,000) for physicians who acquire EMR systems that meet “meaningful use” criteria
 - Inclusion of lab results in certified EMRs will be optional
- Stark Law exceptions & OIG Safe Harbors allow certain entities, including laboratories, to provide their physician office clients with EMR software (expires in 2013)
 - The offices must pay up to 15% of the cost of the software and 100% of the cost of the necessary hardware
 - The software must function *primarily* as an EMR, and must be deemed *interoperable*
 - The EMR donation cannot be tied to referrals
 - Failure to comply can lead to false claims prosecutions
- *Impact: Aggressive laboratory competitors are often willing to use EMR donation as a marketing tool and in ways that do not explicitly meet Stark and Safe Harbor criteria.*