

Healthcare Delivery Reform and the Affordable Care Act: Current Status and Implications for Pathology & Laboratory Medicine

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Objectives

- Provide a brief historical overview of health care reform initiatives
- Review the ACA, its current status and future implementation
- Identify the pathology and laboratory medicine centric components of the ACA
- Review additional policy and legislative initiatives that affect pathology & lab medicine

A Brief Overview of the Long History of Healthcare Reform



While staying out of
the deep “wonky”
weeds

The Long Road to Now

- Theodore Roosevelt campaigns on “social insurance” for “sickness, irregular employment and old age”
- FDR considers health insurance for all but never acts on it
- Truman supports national healthcare insurance but never pushed it
- Eisenhower creates the FEHBP and a tax break for employer-sponsored health insurance in 1954, leading to a proliferation of employer-based plans
- JFK championed Medicare but saw it defeated
- LBJ creates Medicare and Medicaid in 1965, including the Part B FFS model
- Nixon pushes for reform, including an employer mandate and introduces the HMO
- Reagan creates an expansion of Medicare
- George H. W. Bush repeals the Reagan Medicare expansion; proposes an “ACA-like” private insurance model & incentives to improve outcomes and reduce costs
- Clinton tactically fails to get *The American Health Security Act* passed by Congress
- George W. Bush creates the Prescription Drug Benefit for Medicare (Part D)
- Barack Obama passes *The Affordable Care Act*

A “Big, Hairy, Audacious Goal”

“A true BHAG is clear and compelling, serves as unifying focal point of effort, and acts as a clear catalyst for team spirit. It has a clear finish line, so the organization can know when it has achieved the goal; people like to shoot for finish lines.”

J Collins and J Porras,
Built to Last: Successful Habits Of Visionary Companies
1994



Health Reform and the national agenda (slide source: Kaiser Family Foundation)

President Obama at the White House Forum on Health Care Reform, March 5, 2009



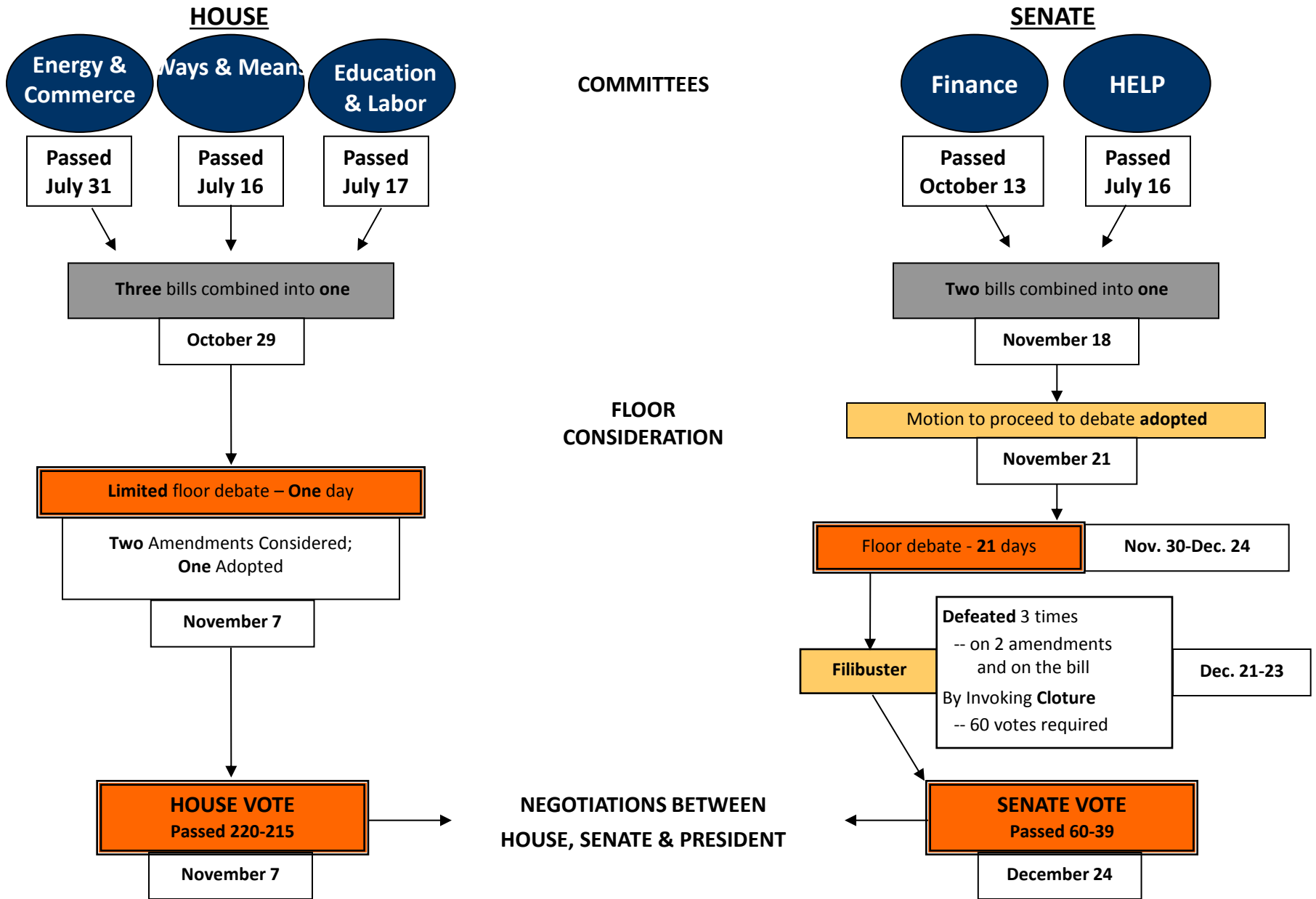
Health reform was at or near the top of the national agenda from the early days of the Obama presidency

“Laws are like sausages, it is better not to see them being made.”

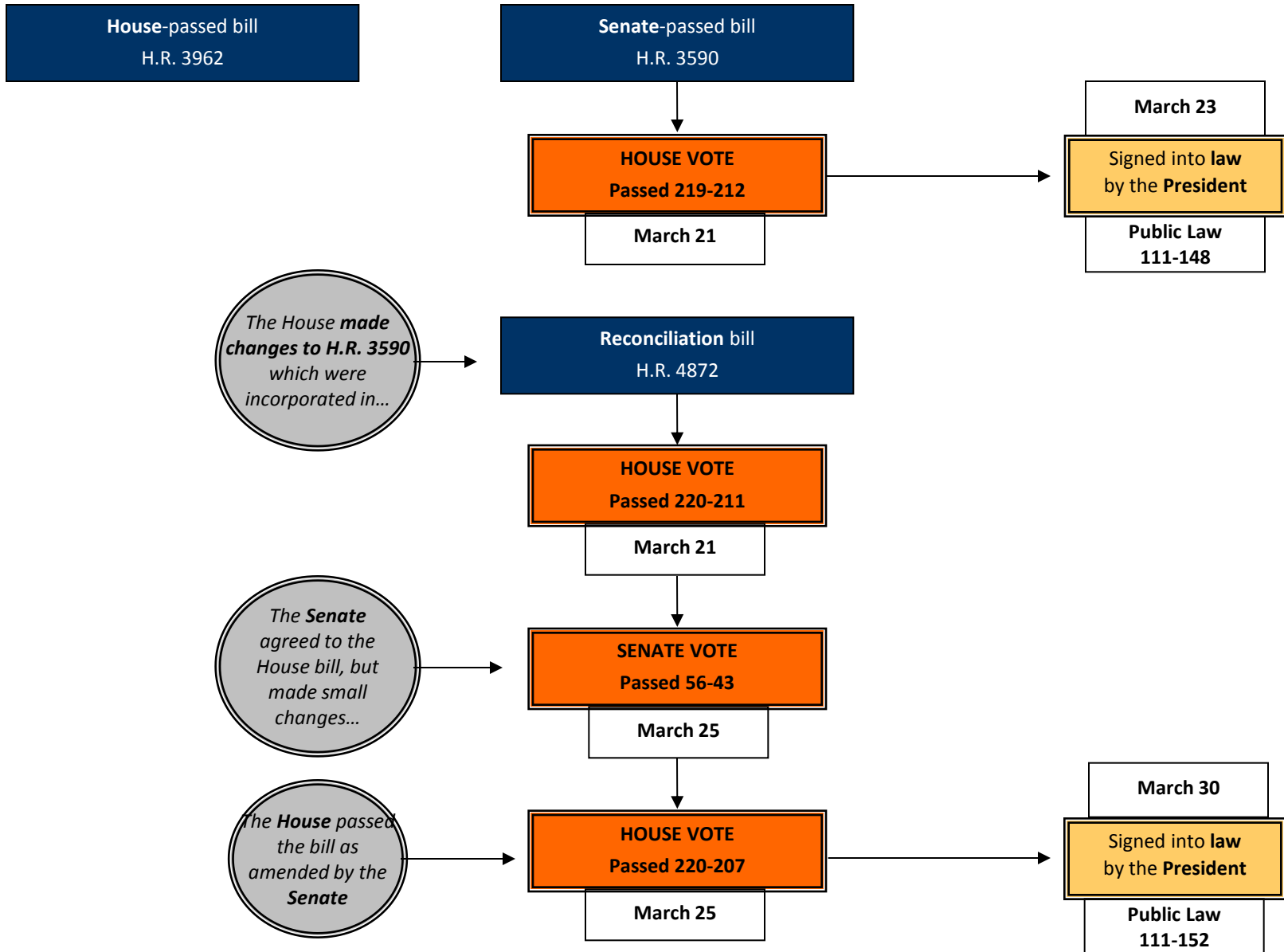
Prussian Statesman and German Chancellor
(1871-1890) Otto von Bismarck (the “Iron
Chancellor”)



Overview - Committees and Floor Debate (2009) (slide source: KFF)



Overview – Resolving Differences and Final Enactment (2010) (slide source: KFF)



Legislation Signed Into Law (slide source: KFF)

- **Health Reform in 2010 – President Obama Signed *two* bills into law**
- **H.R. 3590 – Public Law 111-148**
 - Health reform bill passed by the Senate in December 2009, passed by the House March 2010, and signed into law on March 23, 2010
- **H.R. 4872 – Public Law 111-152**
 - Passed under budget reconciliation procedures by House and Senate; made some changes to P.L. 111-148
 - President Obama signed budget reconciliation bill on March 30, 2010



So, what did this place have to do with healthcare reform?



The US Supreme Court and *The ACA*

- *National Federation of Independent Businesses et al. v. Sebelius, Secretary of Health and Human Services, et al.*, June 28, 2012
 - 5-4 Individual mandate upheld as a tax
 - 5-4 Medicaid expansion upheld, but limited the Federal Government from penalizing States who choose not to participate



The Affordable Care Act

Framework and Cost

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

Essential Elements of the ACA

- Expanding health care coverage
 - Coverage for anyone who wants it
 - The individual mandate broadens the risk pool
 - Subsidies for those who can't afford it
 - But not universal coverage
- Builds on private sector insurance marketplace
 - Create state-based insurance exchanges
(www.healthcare.gov)
- Encourages ways to reduce the growth in spending, through demonstrations, pilots, etc.

ACA Implementation

- Benefits and protections for patients
 - Pre-existing conditions
 - Free preventative care
 - Young adults up to 26 yr stay on their parents' plan
 - Minimum medical loss ratio
 - Cannot cancel policies because of sickness
 - End to lifetime and yearly dollar limits
 - Right to appeal plan decisions
 - Coverage for clinical trials
- Health insurance exchanges
 - State-run (n=17)
 - Federal *healthcare.gov* portal (Oct. 1, 2013)
 - Through private insurers
- Delayed employer mandate (>49 employees)
- Individual mandate begins January 1, 2014
- Medicare Part D “donut hole” discounts
- Free annual wellness visit

“Bending the cost curve?”

- The growth in health care spending is unsustainable
- With full implementation in 2019
 - The Congressional Budget Office (CBO) estimates:
 - Cost of ACA = \$215B per year
 - New revenue = \$230B per year
 - Plus Medicare cost savings projected
 - If Congress preserves and carries out all provisions!



Has Medicare Spending Slowed to a new Baseline?

- CBO 2013 Budget and Economic Outlook
 - New estimates for 2020
 - 15% lower spending projected, independent of any new political action
 - -2.9% excess annual growth, 2015-2018
 - 1.4% per year growth, 2018-2023
 - ~\$400B in savings over the next 7 years
 - Weaker cost drivers?
 - Provider price increase moderation
 - Administrative expenses
 - Technological changes
 - Efficiency
 - Impact of decreased utilization on demand?

Implications and Impacts for Pathology & Laboratory Medicine

CLFS Updates: the ACA and more....

- 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%
 - **1.75% cut in the annual CPI update**
 - Can result in an update <0%
 - **Effect of Sequestration (annual 2% cuts)**
 - **-1.75% CLFS update for 2011**
 - **+0.65% CLFS update for 2012**
 - **- 2.95% and -2.0% Sequester (April 1) CLFS update for 2013**
 - **-0.75% for 2014, plus Sequester?**
 - **Impact of the CLFS “technology update” in the 2014 PFS Final Rule?**

Impact: Pricing and reimbursement pressures will continue.

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

Center for Medicare and Medicaid Innovation

- Charged to drive the development of new payment and service delivery models
- Funded with \$25M/year
- The target agency for demonstrating the pathologist/laboratory medicine value proposition in new payment models (like bundled payments, ACOs and value-based performance for physicians)

National Pilot Program on Payment Bundling

- A national voluntary, pilot program to coordinate care during an entire episode of care (48 episodes of care, >200 DRGs)
 - 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 established 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.

Accountable Care Organizations

- Networks of physicians and other providers held accountable for the **cost and quality** of the full continuum of care to a group of patients.
- 488 ACOs are being tracked as of July 2013 (Leavitt Partners, www.LeavittPartners.com)
 - Medicare ACOs now growing faster (>50% of all ACOs) than non-Medicare; all 50 states covered
 - No single dominant model
 - Mix of fee-for-service, bundled payment and capitation risk-sharing reimbursement models
- “The end of the beginning...”

ACOs, Pathology and Laboratory Medicine

- Promoting more efficient, effective and coordinated use of diagnostic and management resources
 - Coordinated diagnostic management teams, quality and process improvements, IT infrastructure improvements
- Promoting the pathologists' role
 - CAP White Paper "*Contributions of Pathologists in Accountable Care Organizations: A Case Study.*" May 2012
 - Creating a statutory and/or regulatory requirement that ACOs establish clinical laboratory advisory boards, with pathologist leadership
 - State-level initiatives
 - CA Senate Bill 264, IL House Bill 2544, NJ Assembly 4302 based upon the CAP's model legislation

Implication: Pathologists and laboratorians have to be at the ACO planning and implementation "tables" as early as possible

Value-Based Performance (VBP)

- Combines Physician Quality Reporting System (PQRS), EHR Meaningful Use and Value-Based Modifiers into VBP
- Currently these systems are designed in a way that makes it very difficult for pathologists to comply and receive full incentive credit

Impact: VBP pathways for specialties like pathology need to be more flexible and specific to their unique quality activities

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: So far the projected reduction in the growth of Medicare spending means the IPAB may not have to act anytime soon.

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
 - Depends, in part, on the success of healthcare.gov and the statewide insurance exchanges
- 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.

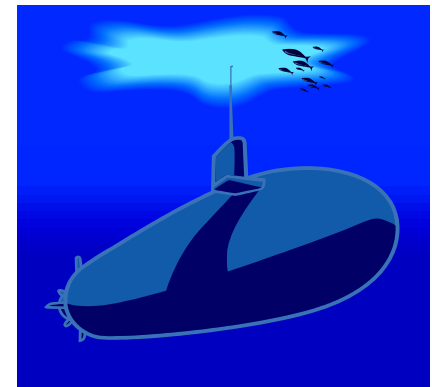
Medical Device Excise Tax

- 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
- Bipartisan support in Congress for eliminating this tax

Impact: Cost passed on to customers. Uncertain whether Laboratory Developed Test's are also subject to the tax.

Other Legislative and Policy Issues of Interest to Pathology & Laboratory Medicine

“Multiple torpedoes in the water
have acquired us!”



We are a target-rich environment...

- Medicare Physician Fee Schedule Final Rule for 2014
- Molecular Pathology CPT Codes (“MoIDx”)
- Self-referral
- Meaningful Use and EHRs
- CLIA Proficiency Test Sanctions
- Laboratory-developed tests and the FDA

Medicare PFS Final Rule

- The annual Medicare Physician Fee Schedule Final Rule is issued by CMS to update payment rates for physician services and other related services like clinical laboratory
 - Sets the physician payment update according to the Sustainable Growth Rate (SGR) formula established in 1997
 - Usually issued on November 1
- Addresses regulatory changes to Medicare and Medicaid services
- Can only be over-ruled by an Act of Congress

2014 PFS Proposed Rule

- Released on July 8, 2013 by CMS
- Limit payments for physician services provided in office settings and independent laboratories
 - Set the rate cap on practice expense (PE) payments to those paid under the hospital OPPS fee schedule
 - Affects 39 pathology codes; up to 75% cuts in TC payments; ~ -26% overall to independent labs and
 - ~ -5% to pathologists
- Adjust payment levels for all tests on the CLFS based upon “technological changes”
 - >1200 test codes over 5 years, beginning with the “oldest and most common” ones
 - Most fee rates would go down
- Over-valued, miss-valued CPT code initiative

Public Comments

- CAP, ASCP, and ACLA (“Apples & Oranges...”)
 - Application of OPPS method (average payment) to the PFS method (resource-based)
 - Oversteps CMS statutory authority
 - Legislative fix if CMS doesn’t drop the hospital OPPS?
 - Revaluing the CLFS in the face of numerous past reductions since 1984
 - Cannot be only used to reduce payments
 - Duplicative of other factors (e.g., ACA’s annual “Productivity Adjustment”)
 - Proposing alternative approaches legislatively
- Congress’ response
 - September bipartisan letter from 113 House offices, October 17th letter from 40 bipartisan U.S. Senators to CMS Administrator Marilyn Tavenner to drop OPPS

2014 Medicare PFS Final Rule

- Released November 27, 2013
 - CMS decides not to cap the PFS to hospital OPPS payment rates
 - Revaluing the CLFS for technological changes will proceed
 - Overvalued, high-volume code payment rates
 - Reduce the TC & PC 88112, delay ISH (88365, 88367 and 88368) decision until 2015; no further cuts to 88305
 - Replace 88342 with G0461 (1st) and G0462 (each added), reduce TC and PC, and restrict to “per specimen” unit of service rather than “per block”
 - New restrictions and new G-codes on prostate biopsies
 - Bundling pathology and lab services into OPPS rates, except for molecular pathology tests

What About the SGR Cuts?

- ~-24% cut programmed by formula for 2014
- Congress has “kicked the can down the road” with temporary (6-12 mo. extensions, freezes, cuts and increases)
- A 10-year fix to replace the SGR has been scored by CBO as costing \$178B
- The three Congressional committees of jurisdiction over Medicare have (or will) propose legislation to fix the SGR cut permanently
 - Realistically the likely scenario is a short freeze/extension in 2014

Molecular Pathology CPT Codes and Reimbursement Policy

- New AMA CPT codes for gene-specific Molecular Pathology were introduced in 2012, replacing the “stacking” methodology codes
 - Tier 1 (81200-81383)
 - Tier 2 (81400-81408)
 - Unlisted 81479
- New AMA CPT codes for Multianalyte Assays with Algorithmic Assays (81500-81599)

CMS MoPath Reimbursement Policy

- CMS did not pursue pricing the Tier 1 & 2 codes until 2013
 - MACs were instructed to price all of these codes by gap-filling rather than cross-walking to the original stacking codes
 - Not all MACs priced all codes (made “coverage determinations”)
 - Little uniformity between MACs
 - CMS set NLA for ~half of codes for 2014; but, why not all and can MACs pay below this if they have priced lower?
 - Will the MoIDx Services Program go nationwide?
 - Developed in 2011 by Palmetto GBA Medicare MAC; sets the administrative policy for reimbursement claims

Physician Self-Referral and Anatomic Pathology

- The physician self-referral (“Stark”) law prohibits physicians from making Medicare referrals for certain ***designated health services*** to entities with which they have a financial relationship.
 - Certain *in-office ancillary services* (IOAS) are exempted DHS, including Anatomic Pathology services
 - Proliferation of schemes in urology, gastroenterology and other specialty medical groups
 - Potential for abuse for financial gain

Evidence for Abuse

- Mitchell JM. Urologists' self-referral for pathology of biopsy specimens linked to increased use and lower prostate cancer detection. *Health Affairs* 2012;31(4):741.
- US Government Accountability Office (GAO). Report to Congressional Requesters: Medicare. Action needed to address higher use of anatomic pathology services by providers who self-refer. June 2013 (GAO-13-445).

Why AP Doesn't Fit the IOASE

- The IOASE was intended to allow the use of and reimbursement for certain ancillary services provided at the time a patient is being seen in a physician's office (e.g., certain clinical laboratory tests)
- AP services cannot, by their nature, be provided at the same time as the patient encounter

Efforts to Address AP IOAS

- CMS has avoided numerous calls over several years to address this issue (“a fight within the House of Medicine”)
 - CMS has monitored the practice for “potential abuse”
 - The Mitchell Study and the GAO Report are making it increasingly problematic for CMS not to act
- Legislative route
 - H.R. 2914 *Promoting Integrity in Medicare Act of 2013* (Rep. J Speier, D-CA; Rep. J McDermott, D-WA)
 - Removes AP and certain other services (including intensity-modulated radiation therapy for prostate cancer) from the IOASE

EMR/EHR Meaningful Use

- The EHR Incentive Program provides incentive payments for certain health care providers to adopt/use EHR technology for patient care.
- To receive the incentive, physicians must demonstrate “meaningful use” of their certified EHR through achievement of specific objectives.
- Penalties for non-participation begin in 2015.
- Physicians can apply annually for a “hardship exemption” (for up to 5 years).
- EHR donation safe-harbor from Stark and anti-kickback prohibitions set to expire Dec 31, 2013

Why Pathologists Can't Meet MU Core Criteria

- Vital signs—record and chart VS
- Smoking—record smoking status
- Allergy list—maintain active allergy list (80%)
- Demographics
- Discharge notes—electronic copy of discharge instructions (50%)
- Patient communication preferences recorded (20%)
- Immunizations—test capacity of EHR to submit edata to registries
- Drug interactions—implement checks
- Prescription generation—eScripts (>40%)
- Advance directives—recorded (50% >65 yo)

Efforts to Address Pathologist MU

- CMS grants a one-year extension for pathologists
- Legislative route
 - H.R. 1309 *Health Information Technology Reform Act of 2013* (Rep. T Price, R-GA; Rep. R Kind, D-WI)
 - Permanently exempt pathologists from MU incentives and penalties, or
 - Extend hardship exception for a total of 10 years, but allow those few pathologists who qualify to receive incentives

CLIA Proficiency Test Sanctions

- CMS long maintained that the CLIA statute required certificate revocation for any lab referral of a PT survey sample, even inadvertent referrals
- *Taking Essential Steps for Testing Act of 2012* (Rep. M Grimm R-NY; Sen. A Klobuchar, D-MN) was signed into law on September 19, 2012
 - Grants CMS discretion in dealing with PT violations and can impose alternative sanctions prior to revocation
- CMS issues a Proposed Rule September 23, 2013

CLIA 1988—Enforcement Actions for Proficiency Testing Referral Proposed Rule

- Includes the *TEST Act* language: “...a laboratory may (as opposed to “must”) have its CLIA certification revoked when CMS determines PT samples were intentionally referred to another laboratory.”
- Narrowly defines exceptions to “intentional” referral
- Divides sanctions into three categories:
 - Most serious violations, including repeated violations (revocation)
 - Referral results received before the PT event closes and after the lab has reported its own results (suspension <1 year if this is not a repeat violation)
 - Referral results received after the PT event closes (payment of a fine)
- Deadline for comments was November 18, 2013

Laboratory Developed Tests and the FDA

- FDA definition: a clinical diagnostic test developed and performed by a single CLIA-certified clinical laboratory that is:
 - of a “non-commercial” nature
 - of low volume
 - a well-established method, and
 - only performed by high complexity laboratories
- For FDA, LDTs=medical devices under the law
 - “safe and effective” standard
- For laboratories, LDTs=medical services

FDA's Concerns About LDTs

- Analytic reliability questioned
- Inconsistent physician interpretation of appropriate use and of results
- Insufficient clinical support for some LDT use claims
- Manufacturers and clinical labs should not be making unfounded claims
- Manufacturers have to obtain a PMN or PMA approval, while labs don't

Lab's Response

- CLIA is and should be the regulatory framework (“accurate and reliable”)
- Manufacturers can choose between IVD and CLIA approval paths
- Labs should not be making unfounded claims
- Labs should provide better information to ordering physicians and patients
- Certain “high risk” tests should have greater oversight through CLIA, with FDA in an advisory role

Current Status

- FDA has written three Draft Guidance Documents for LDT oversight
 - None have cleared review by OMB
 - Political climate is “crowded” and polarized
 - FDA must give Congress 60 day public notification before releasing Guidance Documents
- ACLA files a Citizen’s Petition challenging FDA’s authority to regulate LDTs (June 4, 2013; petition can be viewed at www.acla.com)
- CAP’s Three Tiered (risk based) proposal, including FDA oversight
- Legislative route

LDT-related Legislation

- *Medical Test Availability Act of 2013* (Rep. M Burgess, R-TX)
 - Preserving access to Research Use Only (RUO) products
- *Better Evaluation and Treatment Through Essential Regulatory Reform for Patient Care Act of 2013 DRAFT* (Sen. O Hatch, R-UT)
 - Create a new regulatory framework for IVD Products performed by clinical labs regardless of where they are manufactured
- *H.R. 3207 Modernizing Laboratory Test Standards for Patient Care Act of 2012* (Rep. M Burgess, R-TX; Rep. R Filner, D-CA)
 - Would define LDTs as not being medical devices
 - Has not been reintroduced in the 113th Congress

Take Home Messages

- The ACA is the law of the land, and implementation will continue.
- Pricing & reimbursement pressures remain intense, despite the focus on quality outcomes.
- The impact of the ACA is unpredictable, particularly its long-term effect on demand.
- We need to be informed, and at the discussion table of the new delivery models.
- We need to be vocal with Congress, the Administration, CMS and the FDA.
- We need to support the efforts of our professional organizations (e.g., CAP, ASCP, ACLA, AMP, APF, etc.)

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