“Health Care Developments: Impact on Pathology Practice, and CAP Advocacy Issues”

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ARUP Park City Update CME Course

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Outline

- CMS Payment Reform Initiatives
  - ACOs and SGR (Weiss)
- Current Payment Model Changes
  - 2015 PFS (Miller)
- “Hot Button” issues
  - Direct Billing, Self-Referral & EHR donations (Miller)
  - ICD-10 & FDA Oversight of LDTs (Weiss)
- Advocacy and You
  - Advocacy 101 (Weiss)
  - Pathology-specific issues (Miller, Weiss)
- Open Forum Q&A

Objectives

- The participant will:
  - Understand anticipated shifts in payment model paradigms affecting pathology and lab services reimbursement (including the ACA, SGR, ACOs, CLFS etc.)
  - List specific concerns posing a threat to the practice of pathology and laboratory medicine (including self referral, direct billing, EHR donation etc.)
  - Recognize the role of “grass roots” advocacy (and ways to participate) in affecting policies important to the practice of pathology and laboratory medicine.

CMS Payment Reform Initiatives

Accountable Care Organizations

Sustainable Growth Rate

Accountable Care Organizations (ACO)

- Provider organizations that agree to provide coordinated care to improve patient outcomes and reduce costs (the “Triple Aim”)
- The ACA encourages ACOs for Medicare beneficiaries
  - Medicare Shared Savings Program (MSSP)
    - One-sided risk sharing
    - n=405 (January 2015)
    - 7.2 million enrollees
  - The Pioneer ACO Program
    - Two-sided risk sharing
    - n=19 (original n=32)
  - The Advance Payment ACO
- Private insurance ACOs
  - n > 250

ACO Structure

- Physician, Hospital, or Physician/Hospital ownership and governance
- Shared savings, risk arrangements
  - Migration from FFS to bundled payments and then capitation
  - One-sided risk (bonus payments)
  - Two-sided risk (bonus, penalty)
  - Quality measures as surrogates for outcome

ACOs in Utah

- Regence BC/BS “Total Cost of Care” incentive model
  - Central Utah Clinic, with savings of $1M in the first year
- Utah Physicians Quality Care
  - Created by UMA in 2014
  - Focus on independent physicians with collective bargaining and physician driven quality of care

Role of Pathology & Lab Medicine

- Share accountability for outcomes and system performance
  - May involve financial shared savings formula
- Deliver best performance & pathologist value proposition
  - Traditional triad
    - Quality improvement
    - Cost effectiveness
    - Service improvement
  - Plus
    - Data integration and management
    - Generating actionable medical knowledge
    - Outcomes-focused utilization management
    - Clinical effectiveness

The New Value Paradigm

- Improved patient management
  - Population health management
  - Chronic care management
  - Acute care management
- Improved cost effectiveness
  - Utilization management (both over- and under-utilization)
  - Resources management
  - Risk reduction in the total test process (pre-analytic, analytic, post-analytic process improvements)
- Care coordination
  - Improved connectivity across the continuum of care
  - Systems and information technology integration
  - Improving care transitions

Medicare Physician Reimbursement and the SGR

- Established in the Balanced Budget Act of 1997
  - Adjusts annual growth in PFS based upon actual spending and growth in GDP
    - Annual adjustments (+ or -) made to the Conversion Factor to match target SGR
    - Can only be changed by Congress (the “Doc Fix”)
      - “Kicking the can down the road” delays
        - » January 1, 2014 CF cut (est. 27.4%) averted in Protecting Access to Medicare Act of 2014 until March 31, 2015

PAMA of 2014

- SGR override provision until March 31, 2015
- Delayed ICD-10 implementation deadline until October 1, 2015
- Revaluing the Clinical Lab Fee Schedule (CLFS):
  - Changed to a “Market-based” system for setting the CLFS fees
    - Based on rates paid by private payers to “applicable laboratories”
      - Reporting to CMS beginning January 1, 2016 and every three years thereafter (“how much data is sufficient?”)
    - January 1, 2017: set rates to the weighted private payer median
      - No payment reductions >10% (2017-2019)
      - No payment reductions >15% (2020-2022)
    - Separate methods for:
      - New “advanced diagnostic laboratory tests”
      - Other new tests
        - » Cross-walk or gap-fill methodology

SGR Permanent Fix (the "Doc Fix")

- Bipartisan, bicameral proposals to repeal the SGR and replace it with a "Merit-Based Incentive Payment System" (*SGR Repeal and Medicare Provider Payment Modernization Act* (H.R. 4015, S. 2000))
  - PQRS, VBM and EHR-MU incentive metrics
  - Includes "non-patient-facing professionals" (e.g., pathologists) language, and authority for the SDHHS to develop alternative incentive metrics
  - New metric category ("clinical practice improvement activities")
- Will of Congress to do something? When?

“21st Century Cures” Initiative

- Framework for legislation from House Energy & Commerce Committee (Chairman Fred Upton, R-MI)
  - “Modernized Framework for Innovative Diagnostic Tests”
  - Closing the gap between the science of cures and how these are regulated
- Actively being drafted (bipartisan) for Spring 2015 filing
  - “ACA-sized” bill
  - Placeholder provision on “modernizing” FDA regulation of diagnostics

Current Payment Model Changes

2015 Physician Fee Schedule Final Rule

CPT Code 88342
Immunohistochemical staining

- 2014 review
  - CMS introduces G codes G0461, G0462 to replace 88342
  - G0461 for first immunostain per block
  - G0462 for any immunostains thereafter
  - Requires separate billing procedures for private payers versus CMS

CPT Code 88342
Immunohistochemical staining

- 2015:
  - G codes rescinded
  - 88342 reinstated
  - New code “88341”
    - 88342 for 1st immunostain per specimen
    - 88341 for any immunostains thereafter
    - Expect private payers will adopt similar 2 tier system per specimen for immunostains
  - New code 88344
    - Multiplex immunostains

CPT Code 88342
Immunohistochemical staining

- 88341, 88342, ….88344
- What about 88343?
  - Proposed by AMA RUC in 2013 as a second tier immunostain (similar to 88341)
  - Not adopted by CMS
  - To avoid confusion, omitted from 2015 PFS

CPT Codes
In Situ Hybridization

- 88365 Manual ISH/FISH; first single probe stain
- +88364 Manual ISH/FISH; each additional single probe stain
- 88367 Manual semi-quant ISH/FISH; first single probe stain
- +88373 Manual semi-quant ISH/FISH; each additional probe stain
- 88368 Computer semi-quant ISH/FISH; first single probe stain, manual
- +88369 Computer semi-quant ISH/FISH; each additional single probe stain
- 88366 Manual ISH/FISH; multiplex stain
- 88374 Computer morphometric ISH/FISH multiplex stain procedure
- 88377 Manual morphometric ISH/FISH multiplex stain procedure

Prostate Biopsies

- **New G code - G0416 (regardless of number of specimens)**
- **No longer accepting 88305 and G0416-G0419 for prostate biopsies**
- **Still on CMS "radar" as misvalued service**
  - **Seeking input on payment level for 2016**

PAMA Expanded Misvalued Code Initiatives

- **Protecting Access to Medicare Act (2014)**
- **Expands CMS' misvalued code authority starting in 2017:**
  - **Threatens pathology by targeting:**
    - **Codes billed in multiple unit**
    - **Codes with low RVUs billed together**
    - **Codes with payment differences across sites of service**

2015 Fee Schedule: Specific Pathology Services

CMS proposal to link pathology payment rates to hospital cost data rather than RUC process

- **Different rates for outpatient (APS/OPC) than inpatient (PFS)**
- **CAP persuaded CMS to withdraw in 2013**
- **No 2015 payment changes, but CMS did request more information**
- **CMS seeking comment on using hospital cost data for valuing payment rather than RUC**

“Hot Button” Issues for Pathologists

Self-Referral, Direct Billing & EHR Donations

ICD-10 & FDA Oversight of LDTs

“Self Referral”

- A.K.A. “pod” labs - histology labs and AP services as part of non-pathology practice (G.I., Urology, etc.)
- Stark laws (health care anti-trust) exempts “In-Office Ancillary Services” (eg. rapid strep, glucose, urinalysis, chest X-ray)
- Liberally interpreted (CT scan, radiation therapy, AP services)

“Self Referral”

- Jean Mitchell (Georgetown economist) study [*Health Affairs* 2012 31(4):741-749]
  - self-referring urologists billed Medicare for 72% more prostate biopsy specimens compared to non-self-referring physicians
  - 40% lower cancer detection rate than those who did not self refer

“Self Referral”

- 2013 Government Accountability Office (GAO) study
  - self-referring providers made an estimated 918,000 more referrals for AP services than independent
  - “this increase raises concerns, in part because biopsy procedures, although generally safe, can result in serious complications for Medicare beneficiaries.”

“Self Referral”

- 2014 Office of Management and Budget (OMB):
  - Closing the self referral loophole would save $6.03 billion over 10 years

“Direct Billing”

- As opposed to “client billing”
  - Treating physician charging a patient full price (or more) for a laboratory service they received at a discount.
- Concerns:
  - Cost versus quality motive
  - Incentive to order more tests
  - Violates AMA Code of Ethics principle (not profiting from another’s effort)

“Direct Billing”

- Legislative approaches:
  - Direct billing only - no client billing
  - Anti-markup - client billing for actual cost only
  - Disclosure – client billing for profit, disclosure to patient required

State Laws (as of 6/2014)

- **Direct Billing:**
  Arizona, California, Colorado, Connecticut, Massachusetts, Nevada, New Jersey, New York, Rhode Island, Louisiana, Ohio, South Carolina, Tennessee, Indiana, Iowa, Maryland, Montana, Kansas, Washington
- **AntiMarkup:**
  California, Florida, Michigan, Oregon, Pennsylvania, Utah, Virginia, Washington
- **Disclosure:**
  Arizona, Connecticut, Delaware, Florida, Louisiana, Maine, Maryland, Nebraska, North Carolina, Ohio, Pennsylvania, Texas, Vermont, New Jersey, Tennessee, Utah

EHR Donations

- Another exception (“safe harbor”) to Stark:
  - Permits reference labs to donate up to 85% of the cost of EHR to a client physician office
- “Inducement”, “Kickback”, “Sweetener”
- Smaller local labs disadvantaged
- Pre-2013:
  - MO, NJ, NY, PA, TN, WA, WV prohibit
- 2014: CMS/OIG remove labs from this safe harbor (signficant loopholes remain)

ICD-10 Implementation

- October 1, 2015 deadline
- Implications and unanswered questions:
  - Lack of compliance by physicians submitting laboratory orders without diagnosis codes
  - Comprehensive testing of coding transitions between providers and insurers
  - Conversion of LCD codes
  - Cross-walks between ICD-9 and ICD-10 (“General Equivalence Mappings”), especially those that affect clinical labs

FDA Oversight of Laboratory Developed Tests

- Draft Guidance Documents published October 3, 2014
  - Plan to regulate all moderate- and high-risk LDTs through pre-market review
  - Notification and adverse event reporting
  - 9 year timeline to full implementation initiated when Final Guidance issued
  - 120 day public comment period ended February 2, 2015

FDA's Long Held Views

- Test developed, validated and offered by a single high-complexity lab
- LDTs are medical devices
  - "Safe and effective" standard
- Enforcement discretion exercised
- Legal authority to regulate
- Exceptions for "traditional LDTs" and LDTs used within a single health system

Potential Impact

- Final classification criteria
  - Moderate v. high risk
- Resources necessary for compliance
- Decisions to no longer offer an LDT
  - Patient access
- Stifle innovation
- Method improvements that require re-submissions/approvals

Possible Outcomes

- Final Guidance unchanged from the Draft Guidance
- FDA “moderates” the requirements/process to be less onerous
- Congress stops the FDA from proceeding
- The lab industry sues the FDA

Political Advocacy for Legislative and Regulatory Issues in Pathology and Laboratory Medicine

Influencing Decisions and Making a Difference

Why should I engage in political advocacy?

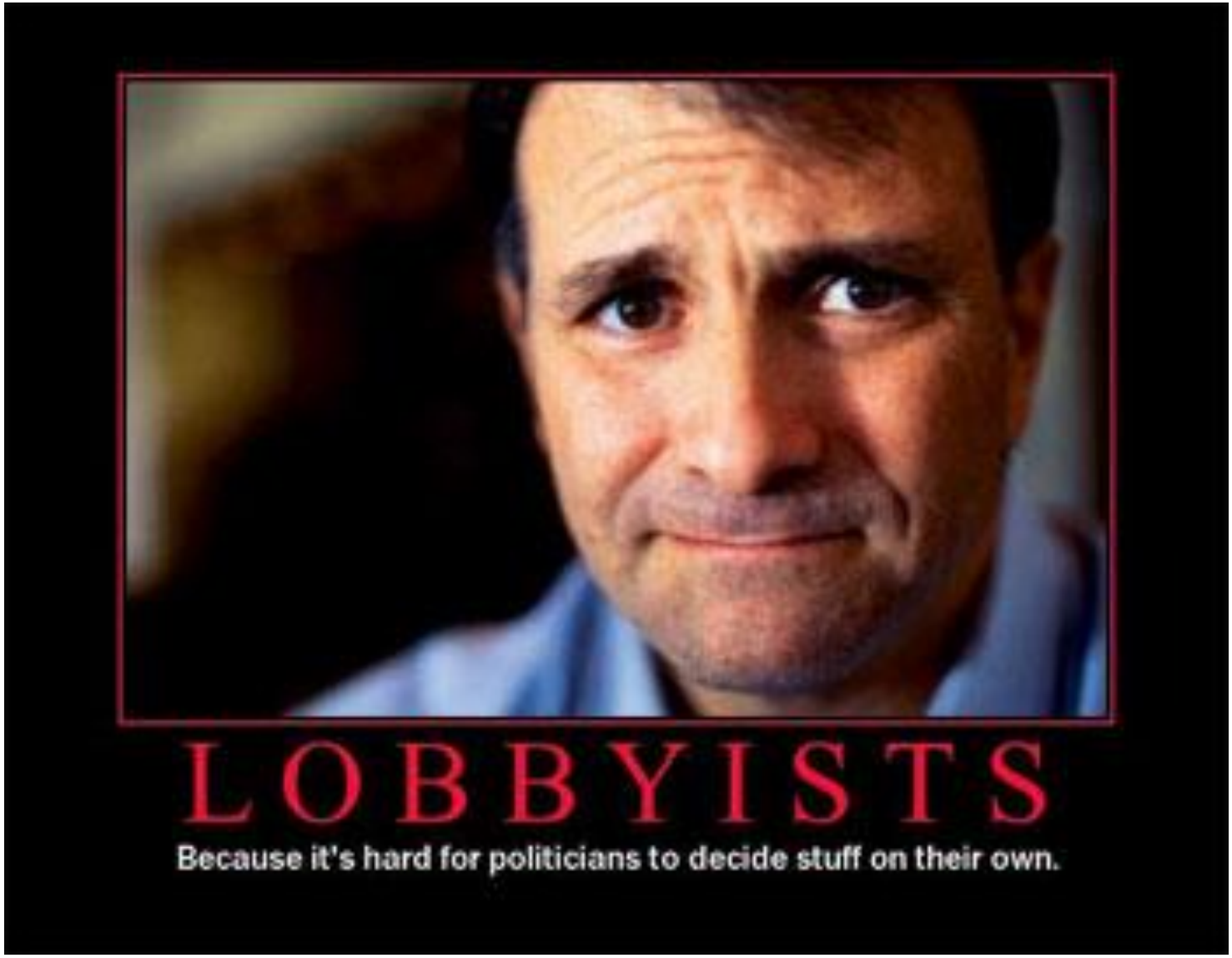
- Policy can enable or disable the future of the specialty
- Pathology must engage to influence its destiny
- If we are not at the table, we are on the menu
- Elected officials represent the people, but are not always fully aware of the needs of their constituents
  - Usually not experts on every issue
  - Depend upon staff and others, including lobbying groups and private citizens, to educate them

Advocacy

- The dissemination of information:
  - To persuade the public and/or public officials
  - To promote a cause and seek support for it
- Educational
- Clarify, dispel inaccuracies and inform

Lobbying

- Advocacy in support of specific legislation
- Attempting to influence or sway a public official towards a desired action or position
- Focuses on decision-makers particularly in Congress, the Executive Branch and Federal Agencies
  - Influence laws and regulations
- Lobbyists represent their clients' interests and guide them through the process
- Lobbyists are generally not…


LOBBYISTS
Because it's hard for politicians to decide stuff on their own.

“Deep pockets speak; the money trumps it all.”

Anonymous lobbyist

2002

Campaign Contributions

- Individual contributions
  - $2,600 to a candidate or candidate's committee per election
  - $32,400 to a national party committee per year
  - $5,000 to a PAC per year
- Political Action Committees

Political Action Committees (PACs)

- A private group organized to elect political officials or to advance the outcome of an issue or legislation
  - Governed by the rules of the Federal Election Campaign Act
- Represents special interest groups (e.g., trade associations), unions or corporations
  - Unions cannot contribute directly from their treasuries, only from their members
  - Corporations can only solicit from executives, employees and their families
- PathPAC
  - Organized Pathology's PAC

PathPAC

- A bipartisan US Congressional Political Action Committee
- The only PAC dedicated to advancing the policy interests of Pathologists
- Allows pathologists to collaborate financially to support candidates for public office

PathPAC Goal

- Be a top 3 Physician Specialty PAC
- Raise $1,000,000 EVERY year
- American Assoc of Orthopaedic Surgeons also has ~15,000 members
  - If surgeons understand the importance of a PAC then so should pathologists!

Who Should I Approach?

- Two direct opportunities for citizens and organizations to influence political decisions
  - Contacts with Members of the Legislative Branch
    - Members
    - Their Staff
    - Testimony at Congressional Hearings
  - Contacts with representatives of the
    - White House
    - Cabinet Departments/Agencies
    - Office of Management and Budget (OMB)

Communicating With a Member

- Telephone calls
  - Usually the least successful ("checking the donor list…")
- Letters/emails to the Member
  - Website example: Senator Orrin Hatch http://hatch.senate.gov/public/index.cfm/email-orrin
- Visiting with a Member/Staff
  - Washington office
  - Local office
  - Your office or organization (e.g., lab tour)

Personal Visits

- Plan carefully
- Make an appointment
- Be prompt & patient
- Be prepared
  - Have talking points
  - Subject briefs to leave behind
- Be political
  - Make a clear connection to their constituents
- Be responsive

Organizations Can Help

- College of American Pathologists
- American Society of Clinical Pathology
- American Clinical Laboratory Association
- Association for Molecular Pathology
- Clinical Laboratory Management Association
- The Clinical Laboratory Coalition
- Coalition for 21st Century Medicine
- AdvaMed Dx

Advocacy for Pathology

- Role of state pathology societies
  - CAP State Issues Advisor group
  - Meeting with State and Federal representatives
- CAP initiatives
  - *Action Alerts* (mobilizing the “grassroots”)
  - Practice management & economic affairs webinars
  - Annual Policy Meeting (May 4-6, 2015)
    - Registration now open (www.cap.org)
    - Includes day of Hill Visits to carry our message
    - Influence policy and, potentially, new law

“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”)

Health Care Reform

The Affordable Care Act of 2010

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*

One Person Can Make a Difference . . .

- James Navin, MD,

  Pathologist, Honolulu, HI
- Neil Abercrombie (D-1st) Hawaii
  - H.R. 976 “The Investment in Women’s Health Act of 1999”
    - To raise Medicare reimbursement for pap smears from $7.15 to $14.60
    - Senate companion legislation: Senators Akaka (D-HI) & Snow (R-ME)

Current Issues for 2015

- Fixing the Sustainable Growth Rate (SGR) formula and the Medicare PFS
- Stark Law self-referral prohibitions and the IOAS exception
- FDA & Legislative actions on laboratory developed tests (LDT)
- Preventing further cuts to the CLFS
- Exempting pathologists from EMR MU criteria

Sharing Our Experiences

- Who is currently engaged in an ACO arrangement? How is it going so far?
- For those outside of Utah, how is your state pathology society engaged in advocacy?
- What is working? What isn't? Where do you need help?
- Share personal success stories, please.

Final questions? Comments?

Thank you for your attention and participation